SmartXIDE

CO_2 laser system

DEKA
Medical Electronics Laser Associated

Operator's Manual

Code: OM079R1_G.V09

Date: 02/09/2009

S/N:

Table of contents

Index of figures

Figure *Page*

Figure *Page*

Index of tables

Table *Page*

Glossary

The following symbols and abbreviations may be used on the SmartXide system and/or in this manual.

Table 1: Symbols and abbreviations

Symbols

	Symbol of non ionizing radiation
	Electrical protection degree
I	Electrical protection type
~	Symbol of alternating current
	Warning on system disposal (Directive 2002/96/EEC).

Abbreviations

J	Joule - unit of measure of energy
mJ	milliJoule - 1000mJ=1J
nm	Nanometer - unit of measure of laser wavelength, 1000nm=1 m
m	micron - 1000 m=1mm
s	Second - unit of measure of time
ms	millisecond - 1000ms=1s
s	microsecond - 1000000 s=1s
min	Minute - unit of measure of time, 1min=60s
Hz	Hertz (cycles per second) - unit of measure of frequency
A	Ampere - unit of measure of electrical current
mA	milliAmpere - 1000mA=1A
VA	Volt-Ampere - unit of measure of absorbed electrical power
W	Watt - unit of measure of power
mrad	milliradian - unit of measure of angles, 1000mrad=1rad
ac	Alternating current
Vac	Volt ac - unit of measure of alternating voltage
Pa	Pascal - unit of measure of atmospheric pressure
NOHD	Nominal Ocular Hazard Distance

Page intentionally left blank.

Introduction

The SmartXide system

The SmartXide system emits a wavelength of 10.6µm, which is highly absorbed by water. Since tissue is comprised mostly of water, this invisible wavelength is highly effective in the surgical treatment of soft tissues.

About the Manual

The SmartXide Operator's Manual provides operators with the following information about the laser:

- ✓ Safety
- ✓ System requirements
- ✓ System description
- ✓ Installation
- ✓ System Operation
- ✓ Use of the control panel
- ✓ Clinical Application
- ✓ Faults and troubleshooting
- ✓ Maintenance
- ✓ Accessories

Although this manual is not intended to be a complete guide, however operators are recommended to carefully read it because it gives useful information on the use and maintenance of the system.

In this manual we use different colours to highlight notes:

notes written in ***blue boxes*** are more detailed remarks;

notes writen in ***yellow boxes*** are remarks which is recommended to read for a correct and safe use of the system;

notes written in ***red boxes*** are remarks which is absolutely necessary to read and follow for a safe use of the system.

CAUTION! **Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.**

Page intentionally left blank.

Warnings

Deka is liable for effects resulting from safety, reliability and performance only if:

- ✓ the equipment is used according to all the instructions contained in this manual (concerning either safety precautions or use of the system);
- ✓ installation, assembly, additions, changes, modifications, repairs and maintenance procedures are made by personnel having proper authorization and qualification;
- ✓ the electrical system in the area designated for the system conforms to IEC and local regulations.

The SmartXide system is medical equipment.
Its major applications are dermatology, ENT, gynaecology.

THE USE OF THE SMARTXIDE SYSTEM IS ALLOWED ONLY TO PHYSICIANS.

Deka is not responsible for direct or collateral effects resulting from therapeutic or surgical use of the system which is a direct responsibility of medical personnel.

Deka commits to supply, upon written request, circuit diagrams, part lists, setting instructions and any information necessary to the maintenance personnel, authorized by Deka, concerning those parts of the system which Deka judges to be reparable.

Page intentionally left blank.

Premises

The instructions below must be carefully followed for the purpose of installing the equipment correctly and so as to avoid risk to the installer and to third parties.

Control of the goods received

Inspect, in the presence of the carrier, the condition and intactness of the goods received. Check that what has been delivered corresponds to what is described in the transport documents. Challenge the carrier with any defect or damage observed.

NOTE

In accordance with the national and international laws, the goods always travel at the customer's risk. Except in the event of different agreement at the moment of drawing up the contract, the goods are always transported without insurance and at the customer's risk.
Any claim for damage due to shipping, transport, loading and unpacking cannot be attributed to Deka.

Working premises

The working premises must conform to the regulations locally in force, both in relation to the electrical system and to the environmental characteristics required when laser equipment is used.

Responsibility

Deka is not responsible for any prejudicial consequences deriving from installation, use and maintenance which does not conform with what is laid down in this manual, or in any case from the failure on the part of the user to adopt all the circumspection, precautionary measures and safety regulations necessary to avoid prejudice of any kind.

Laser Safety Officer

The IEC TR 60825-8 Safety of laser products, Part 8: Guidelines for the safe use of laser beams on humans (2006-12, Second edition) is dedicated to providing guidelines on how the safety aspects of lasers should be taken care of medical practice.
We recommend consulting this guide and adopting the specified measures.
At point 3.1 the guide requires that the responsible organism should appoint a Laser Safety Officer and define the responsibilities of the same.

Page intentionally left blank.

Safety

This chapter provides a short description of the current safety standard taken in account while designing and manufacturing the SmartXide system.
This section also covers specific safety features designed to minimize potential hazards.

1. General safety

The SmartXide system is compliant with the following standards:

- ✓ **Directive 93/42/EEC** concerning medical devices
- ✓ **Directive 2002/96/EC** on Waste Electrical and Electronic Equipment (WEEE)
- ✓ **Standard EN 60601-2-22** - Medical electrical equipment Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment
- ✓ **Standard EN 60601-1** - Medical electrical equipment Part 1: General requirements for safety
- ✓ **Standard EN 60601-1-1** - Medical electrical equipment Part 1: General requirements for safety - 2. Collateral standard: Safety requirements for medical electrical systems
- ✓ **Standard EN 60601-1-2** - Medical electrical equipment Part 1: General requirements for safety - 2. Collateral standard: Electromagnetic compatibility - Requirements and tests
- ✓ **Standard EN 60825-1** - Safety of laser products - Part 1: Equipment classification, requirements and user's guide
- ✓ **Standard EN 14971** - Medical devices - Application of risk management to medical devices

Classifications:

- ✓ According to Directive 93/42/EEC, the SmartXide system is a **Class IIb** device.
- ✓ According to Standard EN 60601-1, the SmartXide system is classified as "**Class I**" with regard to the type of electrical protection, and "**type B**" for the degree of electrical protection.
- ✓ According to Standard EN 60825-1, the SmartXide system is in **Class 4**.

2. Optical hazard

The SmartXide system emits an invisible beam of intense power that can cause serious eye and skin injury with direct or indirect beam contact. Please adhere to the following precautions to minimize optical damage to laser operators, assisting personnel and patients:

- All persons in the room during treatment must wear **protective eyewear**.
  Protective eyewear must comply with the European regulation EN 207 "Personal eye-protectors. Filters and eye-protectors against laser radiation", and possess the following characteristics: OD≥4@ 10.6 µm, spectral transmission level DI 10600 L4.
  Contact your area agent or DEKA company for information on where to find this type of eyewear.
- **Never look directly into the handpiece or into apertures labeled "laser aperture".**
- Mark treatment rooms clearly to avoid unexpected entry during treatment.
  The label shown in Fig. 1 must be put on the external part of each entrance to these areas in order to point out the presence of a laser source inside.

Fig. 1 - Door safety label

This label is provided with the SmartXide system (accessories).

- **Limit entry to the treatment room to only those who assist in treatment and are trained in the use of the equipment.**
- Cover windows and other openings in the treatment room to avoid the inadvertent escape of laser light.
- **Direct the activated laser only at the intended area of treatment.**
- **Remove any metal object such as watches, rings, necklaces and similar items from the operating area and, if possible, do not use reflective instruments or materials.**
  Reflective objects could intercept the laser beam causing a deflection to an area other than the intended treatment area.
  Many surfaces that may seem opaque can actually reflect the 10.6µm CO_2 laser emission wavelength.
- Put the laser into the Standby mode when the laser is not in use (when in Standby mode, the laser beam cannot be inadvertently activated).
- Ensure that all trained staff assisting in the treatment know how to shut down the laser in the case of an emergency.
- **Always remove the key from the keylock switch when the system is switched off and keep it in a safe place.**

3. Electrical Hazard

The SmartXide system uses high voltages. Do not open the protective panels unless you are trained and authorized to do so.

CAUTION! **To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.**

4. Biological Hazard

The laser smoke presents a possible biological hazard. Ablated tissue from the patient is present in the smoke.

CAUTION! **Laser smoke may contain viable particles. Use of a laser smoke evacuator is recommended.**

5. Laser-induced fire hazard

When the laser beam contacts an exterior surface, the surface absorbs the laser energy, which raises the surface temperature, whether the surface is skin, hair, clothes, or any flammable substance. Operators should take the following precautions to prevent a laser-induced fire:

- Use non-flammable substances for such uses as anesthesia, preparing soft tissue for treatment, and cleaning or disinfecting instruments.
- Be especially careful with the use of oxygen. Oxygen accelerates both the severity and the extent of fire.
- Keep a minimum of combustible materials in the treatment room. If treatment requires the use of a combustible material, such as gauze, first soak it in water.
- Prevent singeing or burning when treating an area with hair by wetting the area with water or saline before beginning treatment.
- Always keep a small fire extinguisher and water in the treatment room.

CAUTION!

- ✓ **Never use inflammable gas for gas shield.**
- ✓ **The use of flammable anaesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen should be avoided.**
  Some materials, for example cotton wool, when saturated with oxygen may be ignited by the high temperatures produced in normal use of the laser equipment.
  The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used.
  Attention should also be drawn to the danger of ignition of endogenous gases.

6. Radio frequency interference

The SmartXide system complies with the EN 60601-1-2 standard.
It needs special EMC precautions and needs to be installed according to EMC information provided in this manual - see Appendix A -.
Portable and Mobile RF communication equipment can affect the SmartXide system.

ATTENTION!

The SmartXide system should not be stacked directly on top of other equipment, and other equipment should not be stacked on top of this equipment.
If stacking is necessary, observe the SmartXide to verify normal operation in the stacked configuration in which it will be used.

7. Essential perfomances

According to IEC 60601-1 Ed.3.0 (2005), the following functions are Essential Performances, i.e. performances necessary to keep risk within acceptable limits:

- ✓ ability of the system to prevent any unwanted laser emission;
- ✓ ability of the system to stop laser emission as soon as footswitch is released;
- ✓ ability of the system to maintain laser output power during treatment within ±20% with respect to the set value.

8. Safety labels

The SmartXide system is provided with the safety labels shown in Fig. 2.

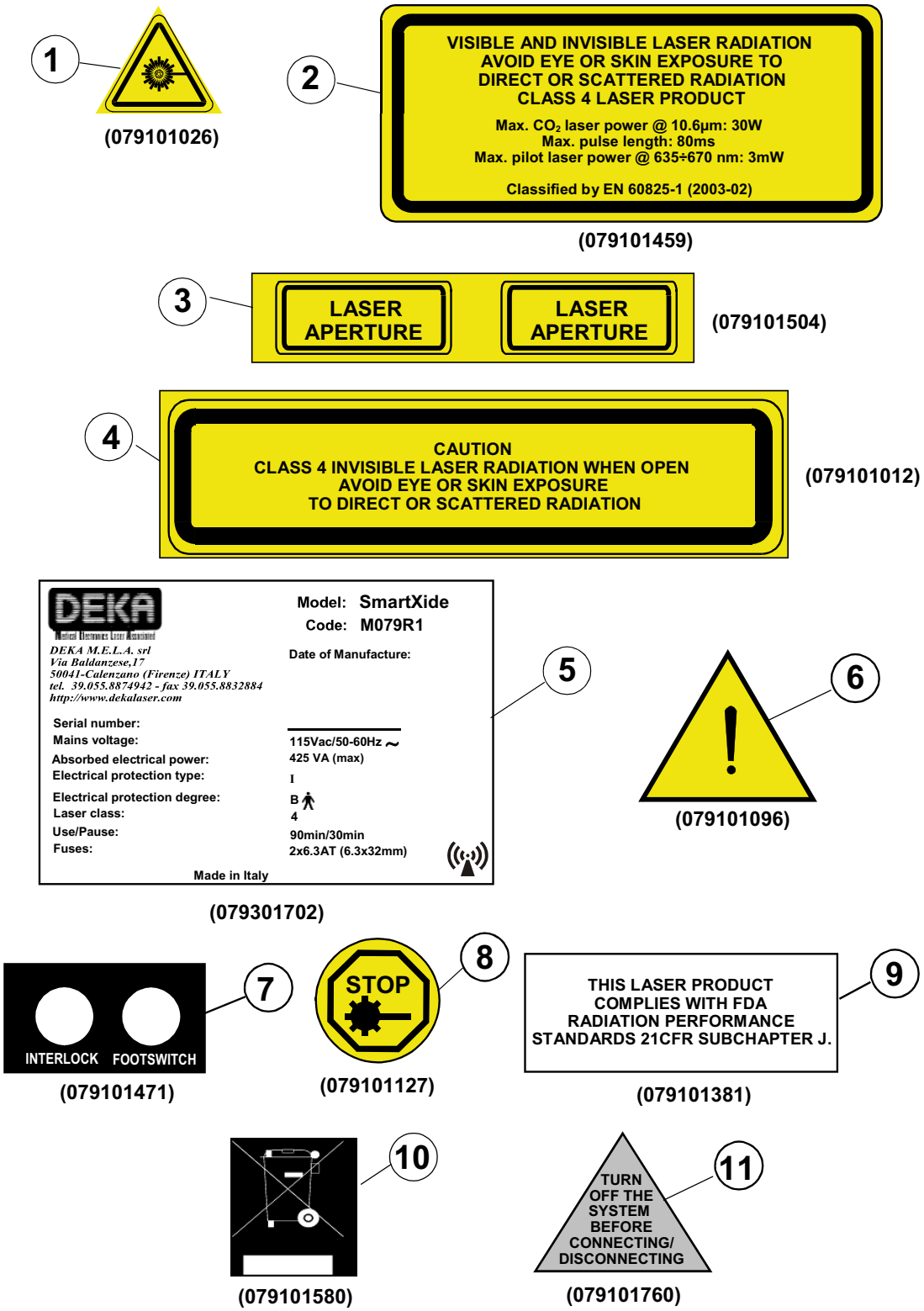


Fig. 2 - Safety labels

8.1.Meaning of the safety labels

Table 1 gives the descriptions of the meanings of the safety labels shown in Fig. 1.

Table 1: Meaning of safety labels

Label Nr	Meaning
1	Emission of laser radiation.
2	Warning on dangers related to the exposure to laser radiation. Specifications on the characteristics of laser radiation.
3	Identifies the aperture from which laser radiation comes out.
4	Warning on dangers related to the exposure to laser radiation in case of removal of panels of the chassis.
5	Identification data for the SmartXide system.
6	Warning. The operator is recommended to read carefully the Operator's Manual before using the system.
7	Identification of the rear panel's connections.
8	Identification of the emergency switch for fast system turn off.
9	CDRH Certification Label.
10	Warning on system discarding (Directive 2002/96/EEC).
11	Warning on DOT Scanner unit connection/disconnection.

NOTE **All the labels must be kept in their own position - see Fig. 3 on page 7 -, in good condition and immediately replaced if damaged.**

8.2. Positions of the safety labels

The safety labels shown in Fig. 2 on page 5 are placed as shown in Fig. 3.

Fig. 3 - Positions of the safety labels

Page intentionally left blank.

System requirements

When preparing the laser site, operators should consider the spatial, electrical, environmental and water requirements of the laser unit.

1. Spatial requirements

The SmartXide system has the following spatial requirements (with the arm in its resting position):

Table 2: Spatial requirements

Height	120 cm
Width	48 cm
Depth	55 cm

2. Electrical requirements

Please consider the following electrical requirements before installing the laser unit:

✓ the AC line power requirements for the SmartXide are:
  115 Vac
  10 A
  50-60 Hz

✓ make sure the socket is efficiently earthed;

✓ the SmartXide system unit should not share a power line with other heavy power-load equipment such as air conditioners or elevators. Ideally, the laser unit should be on a separate power line with a separate circuit breaker;

✓ The SmartXide should not be stacked directly on top of other equipment, and other equipment should not be stacked on top of this equipment.
If stacking is necessary, observe the SmartXide to verify normal operation in the stacked configuration in which it will be used.

3. Environmental requirements

Follow these environmental requirements to properly maintain the laser:

- ✓ keep the air free of corrosive substances, such as salts and acids. These pollutants may damage electrical wiring and optical surfaces;
- ✓ keep dust particles to a minimum. Dust particles can cause permanent damage to optical components;
- ✓ keep humidity in the laser room at 20% to 80%, non-condensing;
- ✓ keep the laser room temperature between 5℃ to 30℃ . Do not place laser unit near sources of temperature variation. When storing the laser system, keep the temperature between 0 to 50℃.

4. Accuracy of values

The accuracy of all the values mentioned in this manual is reported in the outcome of the project for the SmartXide system.

5. Disposal of system

To comply with European Commission Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE) and other country and state regulations, please do not dispose of this equipment in any location other than designated locations.
You can also contact your local DEKA dealer to arrange the return of the equipment to the manufacturer.

System description

This section gives a general description of the interior of the SmartXide system, as well as a more detailed description of the system exterior and specifications.

1. Interior

Although laser operators have minimal contact with the interior portion of the laser unit, an understanding of how the system works may be helpful.

1.1. Laser resonator

The SmartXide laser resonator is a direct current (DC) excited, tube type, sealed-off laser medium (CO_2 gas) laser. When the operator steps on the foot switch, the laser emits either a continuous or pulsed laser beam.
At each end of the resonator are aligned two mirrors. One mirror is 100% reflective, while the remaining mirror reflects only a portion of the beam thus allowing the remainder of the laser energy to pass as useable laser light. The treatment laser beam is combined with an aiming laser (visible) and directed to an articulated arm, which then delivers the two beams to the handpiece.

1.2. Coolant circulation system

A coolant circulation system cools the laser tube to prevent overheating. The pump circulates coolant through the laser head and a heat exchanger. The coolant circulates as long as the laser system is turned on.

1.3. High Voltage Power Supply

The High Voltage Power Supply transforms 115 Vac into high voltage DC.

1.4. Microcontroller

The SmartXide is provided with a microcontroller which manages/controls all the system functions.

1.5. Additional information

Upon request, Deka will provide circuit diagrams, component part lists, descriptions, calibration instructions, or other information not already contained within the manual, to assist appropriately qualified technical personnel to repair those parts of the SmartXide system which are designated by Deka as repairable. "Appropriately qualified technical personnel" in this context refers to personnel who have undergone Deka's Service Training Course for the SmartXide system and have been authorized to repair the laser.

2. Exterior

The operator interacts directly with the following exterior portions of the laser unit:

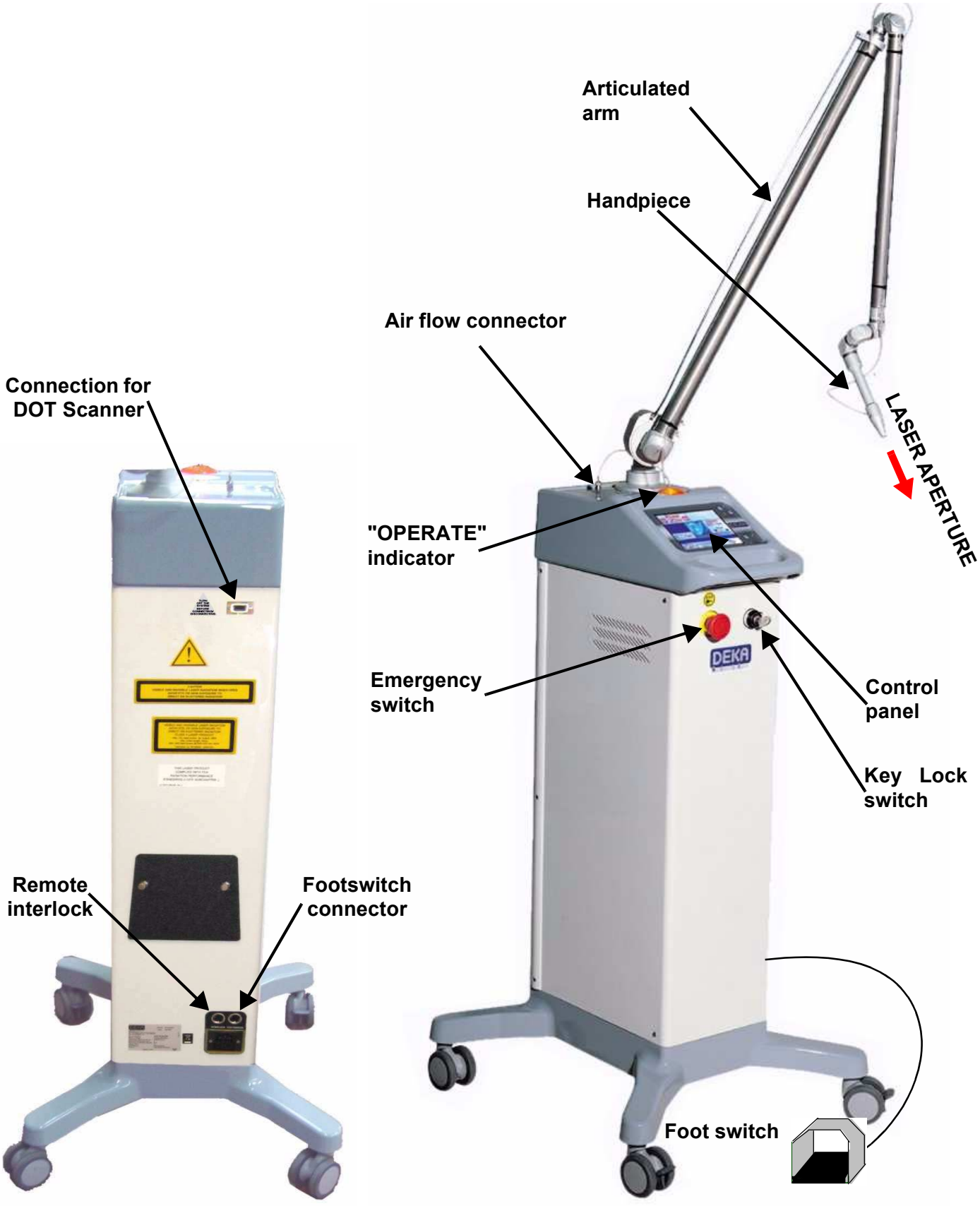


Fig. 4 - System's main external components

2.1.Articulated arm and handpiece

The handpieces shown in Fig. 5 are usually provided with the system.
The minimum available spot size is 0.2mm and it can be obtained with the 50mm handpiece; the term "spot size" identifies the diameter of the laser beam - and therefore the diameter of the circular area exposed to laser radiation - when the handpiece is hold perpendicularly to the surface to be treated and the handpiece's spacer is in contact with the surface itself.

The handpiece is attached to the distal end of the articulated arm, which is a permanently mounted laser delivery system of the SmartXide system.
The articulated arm is an optical assembly that delivers free beam laser radiation. It is made up of seven mirrors placed on rotating knuckles: the mechanical accuracy of the articulated arm allows the CO_2 laser beam to travel inside it and along its axis however the arm is oriented.
The field of action of the articulated arm covers a radius of approximately 80 cm, the transfer efficiency of power is greater than 85%. The loss of 15% is balanced by a suitable calibration of the internal power meter.
An air flow is provided by an internal pump in order to avoid dust and particles deposition on the optics during laser operations.
The inlet connector is connected via a plastic transparent tube to an apposite output connector located on the top side of the system.
Never disconnect the transparent tube.
"As the aiming beam passes down the same delivery system as the working beam it provides a good method of checking the integrity of the laser delivery system. If the aiming beam is not present at the distal end of the delivery system, its intensity is reduced, or it looks diffused, this is a possible indication of a damaged or not properly working system" (EN 60601-2-22).

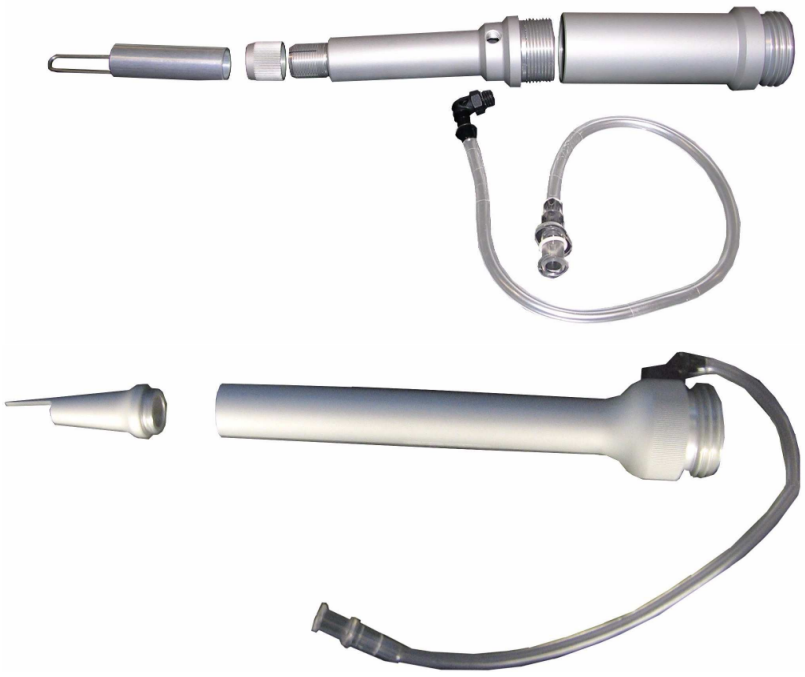


Fig. 5 - Handpieces

Changing handpieces

To change handpieces, disconnect the air purge tubing from the handpiece barrel. Unscrew the handpiece from the articulated arm, see Fig. 5.
Screw on the new handpiece and connect the air purge tubing.

Changing handpiece adaptors

The handpiece adaptor can be easily changed by unscrewing the final part of the handpiece itself and screwing the new adaptor.

2.2.Foot switch

The foot switch allows the operator to control laser emissions.
To connect it, push the connector at the end of the foot switch cord into the socket located on the rear of the laser marked "FOOT SWITCH". Place the foot switch on the floor near the treatment area.

2.3.System Power Controls

The system power controls are comprised of the key switch and the emergency switch, and are described in detail below.

Key Switch

To turn the system on and off use the key switch - see Fig. 4 on page 12 -. It is a double-throw switch (right-left) with removable (***only if it is in the 'O' position***) safety key. To turn the laser on, insert the key and turn the key switch to **I**. To shut the system down normally, turn the key to **O**.

The key switch works to turn on the system only if the emergency switch is not pushed in.

THE KEY MUST ALWAYS BE REMOVED WHEN THE SYSTEM IS TURNED OFF AND MUST BE KEPT ONLY BY AUTHORIZED PERSONNEL.

Emergency Switch

The emergency switch - see Fig. 4 on page 12 - shuts down the system immediately. Use it only under emergency circumstances that is in case it is necessary for the operator to stop immediately laser emission. To shut down the system, push in the switch button. To reset the switch, rotate the button and pull out.

DO NOT USE THE EMERGENCY SWITCH TO TURN ON AND OFF THE SYSTEM UNDER NORMAL CIRCUMSTANCES.

2.4.Control panel

The control panel, detailed in Fig. 6, contains controls and displays for operating and monitoring the system.

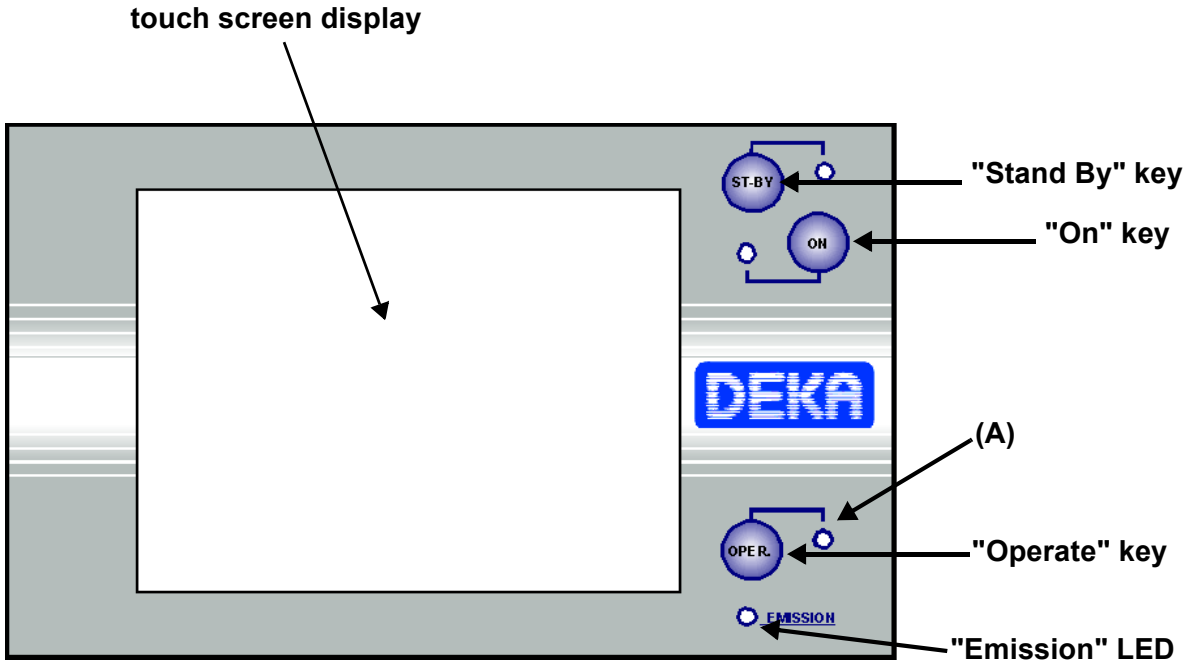


Fig. 6 - Control panel

"ST.BY" key

The STAND BY key allows to switch off the CO_2 laser source.
As this key is pressed, the laser source is immediately switched off. This key is provided with a green LED which is lighted when the source is switched off.

"ON" key

The ON key allows to switch on the CO_2 laser source.
This key is provided with a red LED which is permanently lighted only if the source is switched on.
Note that, only for the CW emission mode, as the ON key is pressed, the red LED may be flashed for a few seconds before being permanently lighted.

NOTE

Automatic switch off of the CO_2 laser source:
if unused for 10minutes, the system automatically switches off the laser source.
This automatic switch off allows to extend the lives of the internal components of the system.

"OPERATE" key

The operator controls laser emissions acting on the system's footswitch.
Footswitch is normally disabled as precautionary measure: if pressed, a warning sound is produced.
The OPERATE key allows to enable/disable footswitch in order to avoid unwanted laser emissions which might occur if footswitch was accidentally pressed when the source is switched on.
Moreover, this key is enabled only if the source is already switched on: if this key is pressed when the source is off a warning sound is produced.

The operator is suggested to use the OPERATE option to disable footswitch while selecting the parameters as a precautionary measure.

The OPERATE key is provided with a red LED - (A) in Fig. 6 - which is lighted only if footswitch is enabled.
Moreover, the system is equipped with an orange lamp - see "OPERATE" indicator in Fig. 4 on page 12 -.

Footswitch is enabled if both these indicator are permanently lighted.

NOTE

- ✓ **During the power evaluation and calibration procedure, both the indicators are switched off.**
  This condition warns the operator that footswitch is ignored by the system, as a safety precaution, until the calibration procedure is completed - see also par. 3. on Section "Use of the control panel" -.
- ✓ **The OPERATE key must always be released and then pressed again in order to make the system change the footswitch's mode.**

Emission LED

The Emission LED, when lit, indicates that the shutter is open and the laser energy is being emitted.

Touch Screen Display

The touch screen allows the user to input commands to the system by lightly pressing an area of the screen itself.

3. System specifications

The SmartXide system is equipped with a CO_2 laser source, emitting an infrared beam, and a diode laser source, emitting a visible red beam.
The diode beam is coaxial with the infrared beam and therefore it is used as an aiming beam.
These two laser sources have the following emission specifications:

Table 3: CO_2 laser source emission specifications

Type	Value
Wavelength	10.6 m
Maximum output power	30 W
Output mode	Multimode
Method of optical output	Articulated arm
Diameter of laser beam (2" handpiece's output)	200 m
Divergence of laser beam (full angle at 2" handpiece's output)	41 mrad
Diameter of laser beam (4" handpiece's output)	400 m
Divergence of laser beam (full angle at 4" handpiece's output)	26 mrad
Power stability (2h:30min)	≤ ±20 %
Nominal Ocular Hazard Distance with handpiece (NOHD)	15 m

Table 4: Diode laser source emission specifications

Type	Value
Wavelength	670 nm
Maximum output power	3 mW
Output mode	Multimode
Method of optical output	Articulated arm
Diameter of laser beam	4 mm
Divergence	0.8 mrad

Table 5: General specifications

Type	Value
Mains voltage	115Vac single phase, 50-60Hz
Absorbed electric power	425 VA (max)
Fuses	2 x 6.3AT (6.3x32mm)
Dimensions	55x48x120 (DxWxH) cm
Weight	approx. 30 kg
External connections	Foot switch Remote interlock DOT Scanner - external scanner unit -
Cooling circuit	Sealed with a liquid/air heat exchanger
Electrical protection degree	B 
Electrical protection type	I
Laser class	4
Ionizing radiation	No
Safety eyewear required	OD≥4 at 10.6 m, DI 10600 L4
Protection against anaesthetics	No
Mechanical stability	10°

Table 6: Operating and environmental conditions

Operating temperature	From 5℃ to 30℃
Operating humidity	From 20% to 80%
Atmospheric pressure	From 70000Pa to 106000Pa
Use	Intermittent: use 90min, pause 30min

Table 7: Storage and transport conditions

Storage temperature	From 0℃ to 50℃
Temperature during transport	From 0℃ to 50℃
Humidity	From 10% to 90%
Atmospheric pressure	From 70000Pa to 106000Pa

Table 8: Operating characteristics

Type	Value
Aiming Beam	Visible. Intensity selectable between OFF and 100%, step: 2% between OFF and 10%, step: 10% for the other values.
Power indication	Digital: value displayed on the screen of the control panel.
Operating modes	✓ **Continuous mode** - CW -: the *output power level* can be selected between 2W and 30W step 1W. ✓ **Pulsed mode** - PW -: the *pulse repetition rate* (frequency) can be selected among the following values: 5Hz, 10Hz, 20Hz, 50Hz, 80Hz, 100Hz; the *pulse length* can be selected via the "Level" parameter: see Table 9.
Exposure modes	Continuous exposure mode or timed exposure mode. The timed exposure mode allows both single exposure ("s.sh.") or repeated exposures ("rep."). When timed exposure mode is selected, the exposure time can be selected between 0.1s and 0.9s. When the repeated exposures mode is selected the delay between two exposures is 400ms and cannot be modified.
CO_2 laser shutter	Controlled by footswitch.

Table 9: Available pulse lengths in PW emission mode

FREQUENCY	LEVEL	CURRENT PULSE LENGTH (see the note below)	LEVEL	CURRENT PULSE LENGTH (see the note below)
5Hz	0.5	1ms	9.0	18ms
	1.0	2ms	10	20ms
	1.5	3ms	11	22ms
	2.0	4ms	12	24ms
	2.5	5ms	13	26ms
	3.0	6ms	14	28ms
	4.0	8ms	15	30ms
	5.0	10ms	20	40ms
	6.0	12ms	30	60ms
	7.0	14ms	40	80ms
	8.0	16ms		

continued on next page...

Table 9: Available pulse lengths in PW emission mode

FREQUENCY	LEVEL	CURRENT PULSE LENGTH (see the note below)	LEVEL	CURRENT PULSE LENGTH (see the note below)
10Hz	0.5	0.5ms	9.0	9ms
	1.0	1ms	10	10ms
	1.5	1.5ms	11	11ms
	2.0	2ms	12	12ms
	2.5	2.5ms	13	13ms
	3.0	3ms	14	14ms
	4.0	4ms	15	15ms
	5.0	5ms	20	20ms
	6.0	6ms	30	30ms
	7.0	7ms	40	40ms
	8.0	8ms		
20Hz	0.5	0.25ms	9.0	4.5ms
	1.0	0.5ms	10	5ms
	1.5	0.75ms	11	5.5ms
	2.0	1ms	12	6ms
	2.5	1.25ms	13	6.5ms
	3.0	1.5ms	14	7ms
	4.0	2ms	15	7.5ms
	5.0	2.5ms	20	10ms
	6.0	3ms	30	15ms
	7.0	3.5ms	40	20ms
	8.0	4ms		

continued on next page...

Table 9: Available pulse lengths in PW emission mode

FREQUENCY	LEVEL	CURRENT PULSE LENGTH (see the note below)	LEVEL	CURRENT PULSE LENGTH (see the note below)
50Hz	0.5	Level not available	9.0	1.8ms
	1.0	Level not available	10	2ms
	1.5	0.3ms	11	2.2ms
	2.0	0.4ms	12	2.4ms
	2.5	0.5ms	13	2.6ms
	3.0	0.6ms	14	2.8ms
	4.0	0.8ms	15	3ms
	5.0	1ms	20	4ms
	6.0	1.2ms	30	6ms
	7.0	1.4ms	40	8ms
	8.0	1.6ms		
80Hz	0.5	Level not available	9.0	1.2ms
	1.0	Level not available	10	1.3ms
	1.5	Level not available	11	1.4ms
	2.0	0.25ms	12	1.5ms
	2.5	0.32ms	13	1.6ms
	3.0	0.38ms	14	1.8ms
	4.0	0.5ms	15	1.9ms
	5.0	0.63ms	20	2.5ms
	6.0	0.75ms	30	3.8ms
	7.0	0.88ms	40	5ms
	8.0	1ms		

continued on next page...

Table 9: Available pulse lengths in PW emission mode

FREQUENCY	LEVEL	CURRENT PULSE LENGTH (see the note below)	LEVEL	CURRENT PULSE LENGTH (see the note below)
100Hz	0.5	Level not available	9.0	0.9ms
	1.0	Level not available	10	1ms
	1.5	Level not available	11	1.1ms
	2.0	0.2ms	12	1.2ms
	2.5	0.25ms	13	1.3ms
	3.0	0.3ms	14	1.4ms
	4.0	0.4ms	15	1.5ms
	5.0	0.5ms	20	2ms
	6.0	0.6ms	30	3ms
	7.0	0.7ms	40	4ms
	8.0	0.8ms		

NOTE

The "current pulse length" values listed in previous table regard the current commands in the laser tube.
The laser pulse lengths are reported in the outcome of the project.

Installation

This section of the manual explains how to install the system.

1. Installation

Proceed as follows:

1. insert the key in the key lock switch located on the front side - see Fig. 4 on page 12 -: the key can be inserted only in the "O" position, so the system is still switched off.
   Do not turn the key to the I position.
2. make sure the emergency switch - see Fig. 4 on page 12 - is pulled upwards;
3. connect the external interlock network to the socket marked "INTERLOCK" - see Fig. 4 on page 12 -;
   if there is no external interlock chain, connect the interlock connector supplied with the accessories (see also the paragraph "Remote Interlock" of this section).
4. connect footswitch to the socket marked "FOOTSWITCH" - see Fig. 4 on page 12 -.

CAUTION!

The contacts of the "INTERLOCK" and "FOOTSWITCH" sockets must never be connected to the mains otherwise the system should be seriously damaged.
Connect these sockets only as specified in this paragraph.

5. connect the mains cable provided with the system to the proper socket located on the bottom rear side of the system;
6. connect the other side of the mains cable to a wall outlet.

NOTE

- ✓ **Make sure the wall outlet is properly grounded.**
- ✓ **Make sure that the mains specifications are met: see Table 5 on page 18 and label n. 5 of Fig. 2 on page 5.**

1.1.Articulated arm installation

Proceed as follows to install the articulated arm:

1. remove the articulated arm (Fig. 7) from its resting position and rotate it clockwise (1);
2. when the spring is tensed, press the retainer downwards (2);
3. to return to the resting position, rotate slightly clockwise (1), release the retainer (3) then rotate counterclockwise up to the resting position (4);

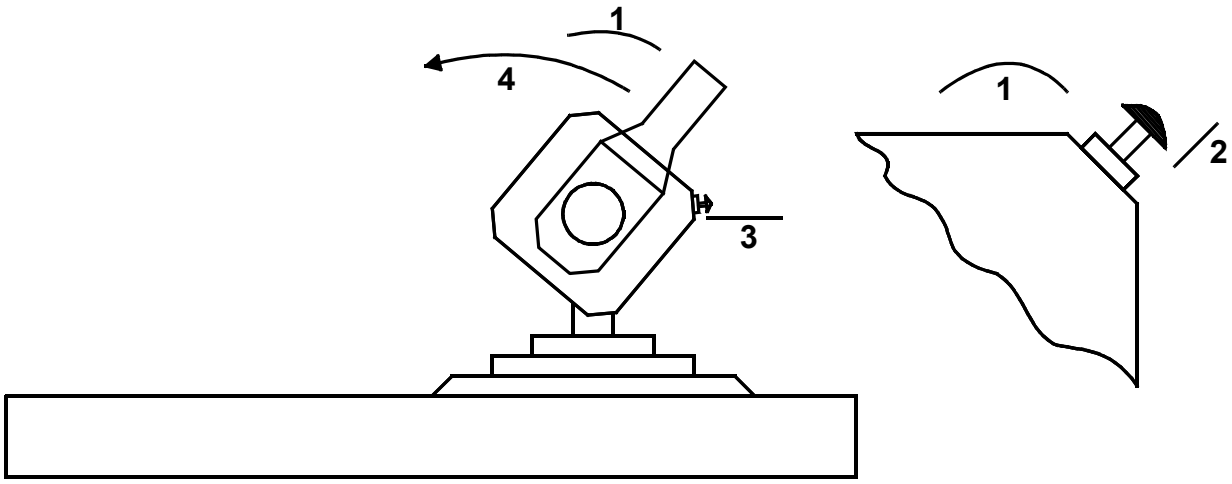


Fig. 7 - Articulated arm

1.2.Air flow connections

The SmartXide system is equipped with an internal pump which produces a continuous air flow which prevents dust and particles from depositing on the optics during laser operations.
On the top side of the laser head enclosure - see Fig. 4 on page 12 - there is the air flow outlet connector: an internal connection links the air pump to this connector.
A plastic transparent pipe is then provided to connect this outlet connector to the inlet connector located on the handpiece: see Fig. 5 on page 13.

NOTE **Always verify that the plastic transparent pipe is properly connected to both connectors.**

1.3.Installation of the DOT Scanner (*optional*)

An optional of the SmartXide system is the unit called DOT Scanner - Fig. 8 - and described in par. 2. on Section "Use of the control panel".
Proceed as follows to install the DOT Scanner, if present:

1. ***turn off the SmartXide system;***
2. remove the handpiece from the articulated arm, if connected;
3. screw the DOT Scanner to the articulated arm;
4. connect the cable - provided with the unit - to the DOT Scanner: insert the connector making the red dot marked on it match with the red dot on the unit connector;

Fig. 8 - DOT Scanner

5. connect the DOT Scanner plastic transparent pipe - see Fig. 4 on page 12 - to the plastic transparent pipe of the articulated arm;
6. connect the other side of the cable to the DOT Scanner connector on the back panel of the SmartXide system - see Fig. 4 on page 12 -.

The SmartXide system automatically detects the presence of the DOT Scanner and allows to activate it via the control panel.

ATTENTION!

The connection/disconnection of the cable to the DOT Scanner and to the SmartXide system has to be performed with the system switched off (*key switch has to be in the 'O' position).*
Non-observance of this condition invalidates the system warranty.

2. Remote Interlock

The interlock socket can be used as an additional precautionary measure to stop laser emissions in case a specific external event occurs.
For instance, all the doors leading to the system operating area can be provided with series-connected micro switches (normally closed). In this case the opening of any of these doors results in an "INTERLOCK ALARM" message (see Sezione "Faults and troubleshooting") so laser emission is immediately stopped.

To connect an external interlock chain, the interlock connector supplied with the accessories can be used. Note that this connector has a jumper between contacts 1 and 2 (set by factory).

Proceed as follows:

1. remove the jumper between the contacts 1 and 2;
2. connect these contacts to the external network.

Note that the interlocks must be normally closed in order to let the laser system operate otherwise an INTERLOCK fault is stated and the system is stopped.

NOTE

- ✓ **No voltage level should be applied to the contacts of the interlock connector.**
- ✓ **If no external interlock chain is to be used, the interlock connector provided with the SmartXide system (accessories) must be connected to the interlock socket in order to disable the interlock fault.**

System operation

This section of the manual explains how to start and to turn off the system and how to calibrate the laser power output.

1. System start-up

Follow the procedure below to start the system:

1. insert the key into the key switch and turn it to "I". The system enters a self-test phase during which the introductory screen shown in Fig. 9 is displayed.

Fig. 9 - Screen at start up

Once the internal check is over, if any problem is detected system displays a SYSTEM FAULT menu - see the Sezione "Faults and troubleshooting" to correct any problems -; if no fault is detected, the system displays the preliminary screen shown in Fig. 10.

NOTE

During the self-test phase, all the LED of the control panel and the lamp on the top cover of the system are flashed in order to let the operator verify they are properly working.
The operator is recommended to verify that either the lamp or the LED indicators are flashing during this phase and call Technical Assistance in case of problems.

2. Press the  icon to enter the SET UP menu;
press the "Start" area to access the USER menu.
See the next section for details.

Fig. 10 - Preliminary menu at start-up

The system automatically selects the following status:

STANDBY mode;

footswitch disabled;

aiming source activated;

exposure parameters previously saved;

emission parameters previously saved.

3. select appropriate emission mode and parameters along with the treatment;
4. press the ON key and wait for the red light to stop blinking;
5. wait for the calibrating procedure to be completed;
6. once the ON key remains lit, press the OPERATE key to enable the foot switch;
7. the laser system is now ready to use. Step on the foot switch to start treatment.

2. Laser power during treatment

Once you have calibrated the laser power output to the appropriate level for treatment, you may begin treating the patient. During treatment, the system constantly monitors the laser power and compares it to the calibrated power setting.
If during treatment the laser power increases or decreases by more than 20% of the calibrated power output, the displayed value changes to current detected power and the warning tone rate increases. If the foot switch remains active, treatment is uninterrupted.

3. "EMISSION" led

The red indicator marked with the label "EMISSION" and located at the bottom right side of the control panel, shows the current state of the laser shutter and is lighted only when laser emission is in progress.

4. Internal buzzer

The system is equipped with an internal buzzer which produces an acoustic signal of fixed length. This unit is used in the following cases:

- ✓ To warn the operator in case a wrong action has been performed - for instance, if footswitch is pressed when disabled -.
- ✓ If a laser treatment is in progress - CO_2 source switched on, footswitch enabled and pressed, shutter open, *real power level correct* - a sound is produced every 1s.
  This timed sound is intended to help the operator to 'measure' the treatment time.
- ✓ If a laser treatment is in progress - CO_2 source switched on, footswitch enabled and pressed, shutter open, *power level mismatch* - five sounds are produced every 1s.
  This faster timed sound is intended to warn the operator that a power mismatch has been detected, that is the real CO_2 output power level nomore matches with the power level found by the power evaluation procedure.
  See par. 3. on Section "Use of the control panel" for further information.

5. Idle mode

If the system is unused for five minutes and no key is pressed, it runs at idle and displays the screen shown below:

Fig. 11 - Screen during idle mode

Touch any area of the screen to end the idle mode.

6. System shutdown

To shut down the laser in a normal, non-emergency, situation, proceed as follows:

1. press the "STAND BY" key on the control panel;
2. turn the key of the key switch to the "O" position

In an emergency, press the emergency switch - see par. 2.3. on Section "System description" -.

ATTENTION! **Always remove the key from the key switch and keep it in a safe place in order to prevent unauthorized use of the system.**

Use of the control panel

The control panel allows the user to control the SmartXide system.
This chapter provides a detailed description of the available functions of the control panel.

1. SET UP menu

The SET UP menu allows to set the system clock and date, to regulate the brightness of the screen and to select the language. Fig. 12 shows an example of the SET UP menu.

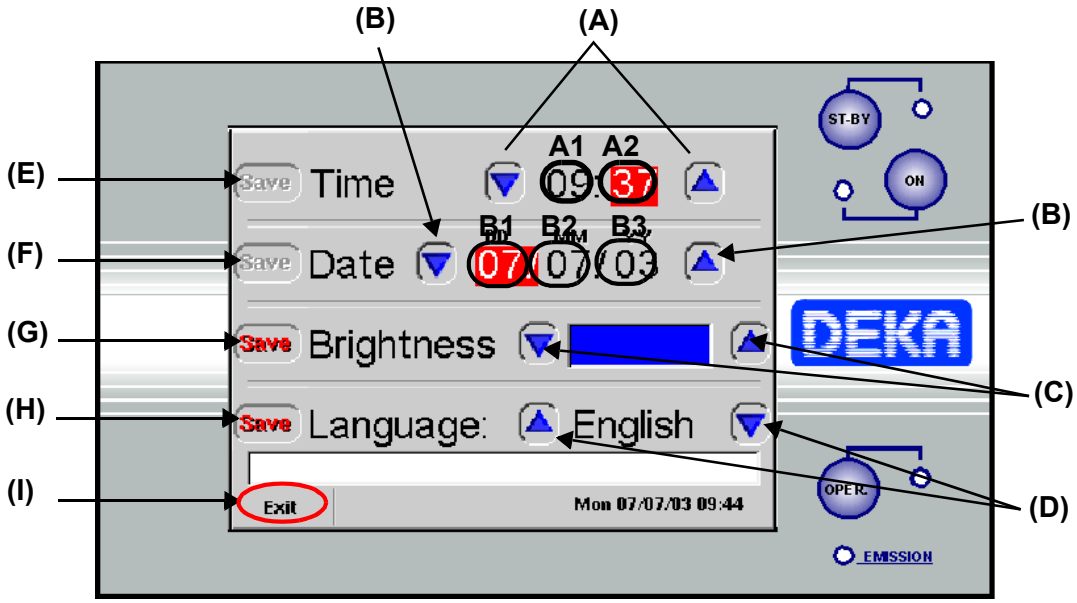


Fig. 12 - SET UP menu

✓ **Clock setting**

Press keys **(A)** to change hour and minute selected by pressing areas **A1** or **A2** respectively. The parameter to be changed is highlighted with white characters on red screen - see Fig. 12 -.
When a parameter is changed, the **Save** option - **(E)** in Fig. 12 - is enabled: press it to save changes.

✓ **Date setting**

Touch keys **(B)** to change day, month or year selected by keys B1, B2 or B3 respectively.
The parameter to be changed is highlighted with white characters on red screen - see Fig. 12 -.
When a parameter is changed, the **Save** option - **(F)** in Fig. 12 - is enabled: press it to save changes.

✓ **Brightness setting**

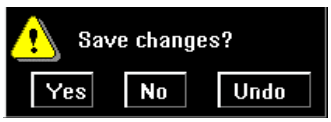
Press key **(C)** to change brightness: it is possible to see on the screen as its brightness is changed.
Use the **Save** option - **(G)** in Fig. 12 - to save changes.

✓ **Language setting**

Use keys **(D)** to change language.
Use the **Save** option - **(H)** in Fig. 12 - to save changes.

✓ **Exit**

Use this option - key **(I)** in Fig. 12 - to quit the menu and enter the PRELIMINARY menu. If some changes were not saved the program will ask if the user intends to save them.



Press "Yes" to save changes and quit; press "No" to go back to the PRELIMINARY menu without saving changes; press "Undo" to go back to the SET UP menu.

2. USER menu

The USER menu contains controls and displays for changing the system's operating parameters. The available parameters depends on the selected emission mode as shown in Fig. 13 and Fig. 14.
A detailed description of each parameter is detailed in the next paragraphs.

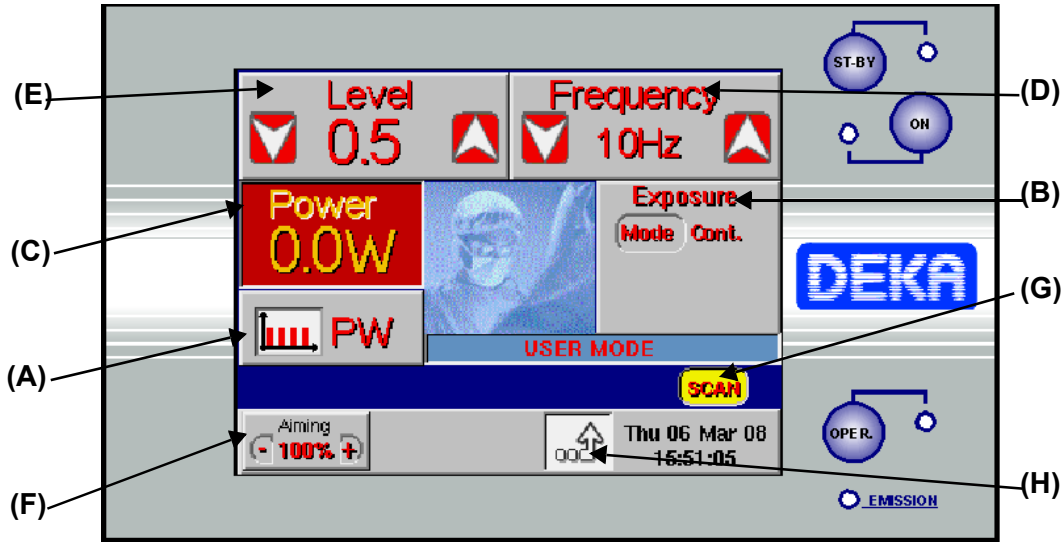


Fig. 13 - USER menu when PW mode selected

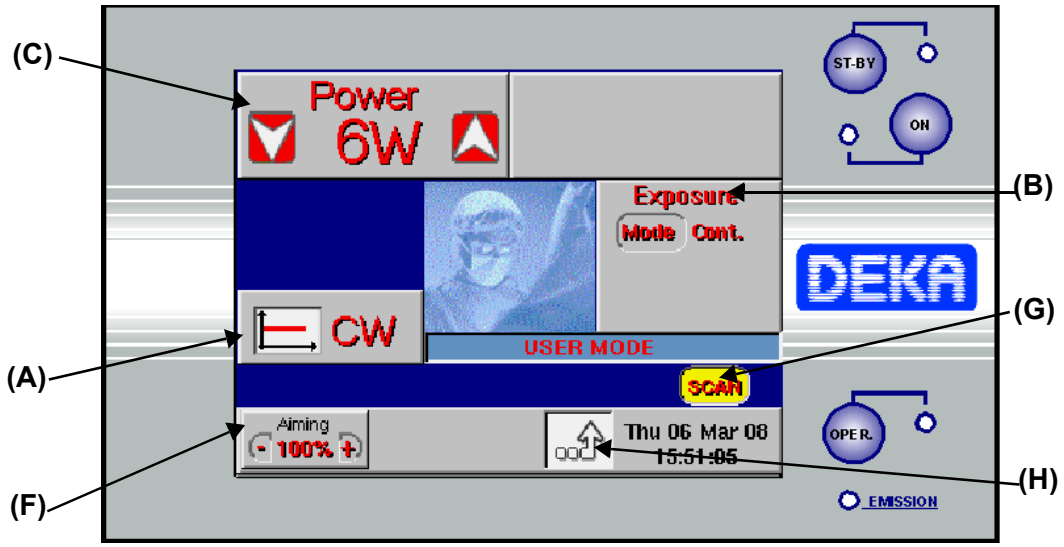


Fig. 14 - USER menu when CW mode selected

1.1. Emission mode

The area **(A)** in Fig. 13 e in Fig. 14 alternately selects and displays either CONTINUOUS (CW) or PULSED (PW) emission mode.

In ***CW mode***, laser emission is continuous: the CO_2 laser source is enabled to emission as long as it is switched on, so it provides a constant output power level whose value has to be selected by the operator according to the treatment to be performed - see Fig. 14 -.
See also par. 3. in this Section for the description of the power evaluation and calibration procedure performed by the system when CW mode is selected.

In ***PW mode*** the CO_2 laser source is pulsed that is it is turned on and off as long as it is switched on.
The operator can select the pulse repetition rate - that is how many times per second the source is switched on and off - and the pulse length.
When the PW mode is selected, the screen changes as shown in Fig. 13.
Note that the operator cannot directly select the output power level, he can change it only acting on the frequency and level parameters.
When the CO_2 source is switched off, the value 0.0W is displayed.
As the CO_2 is switched on, the SmartXide system evaluates the real output power level delivered by the CO_2 source and displays the result on the screen. Moreover, only the average output power level is estimated and displayed.
See also par. 3. in this Section for the description of the power evaluation procedure performed by the system when PW mode is selected.

1.2. Exposure

The SmartXide system allows to control the exposure time during a laser treatment acting on the CO_2 shutter.
The selected exposure mode is displayed on the screen in the "Exposure" area - **(B)** in Fig. 13 e in Fig. 14 -.
Touch this area to change the exposure mode.
Three exposure modes can be selected:

- ✓ continuous - "Cont." on the screen -;
- ✓ timed single exposure - "s.sh." on the screen -;
- ✓ timed repeated exposures - "rep. " on the screen -.

Note that the emission mode - CW/PW - can be changed regardless of the selected exposure mode.

Continuous exposure mode

In continuous exposure mode, the exposure time is fully controlled by the operator acting on footswitch: as long as footswitch is kept pressed, the shutter is open and therefore laser emission occurs.

Single exposure mode

When the single exposure mode is enabled and footswitch is pressed, the SmartXide system opens the shutter and keeps it open only for the selected exposure time.
Once the selected exposure time is exhausted, the shutter is automatically closed regardless if footswitch is still pressed.
If the operator wants to perform a new exposure, he has to released and then pressed again footswitch.
The system displays the selected exposure time below the label "Exposure" - **(B)** in Fig. 13 and in Fig. 14 - and displays two keys in order to change this value between 0.1s and 0.9s (resolution: 0.1s).

Timed repeated exposures mode

When timed repeated exposures mode is enabled and footswitch is pressed, the SmartXide system opens the shutter and keeps it open for the selected exposure time.
Once the selected exposure time is exhausted, the shutter is automatically closed then, if footswitch is still pressed, the system waits for 400ms. After 400ms the shutter is open again and a new exposure is performed. This sequence is continuously repeated as long as footswitch is kept pressed.

The system displays the selected exposure time below the label "Exposure" - **(B)** in Fig. 13 and in Fig. 14 - and displays two keys in order to change this value between 0.1s and 0.9s (resolution:0.1s).
Note that the delay between two exposures is preset by factory to 400ms and it cannot be modified by the operator.

1.3.Power

The POWER select keys - **(C)** in Fig. 14 - increase or decrease and displays power from 2W to 30W in 1W increments. These keys appear only when the CONTINUOUS (CW) emission mode has been selected. See par. 3. in this Section for the description of the power evaluation and calibration procedure performed by the system each time the power level is changed when the CO_2 source is switched on.

1.4.Frequency

The FREQUENCY area - **(D)** in Fig. 13 - displays frequency of laser emission; the FREQUENCY select keys increase or decrease it from 5Hz to 100Hz. These keys appear only when the PULSED (PW) emission mode has been selected.
See par. 3. in this Section for the description of the power evaluation and calibration procedure performed by the system each time the frequency is changed.

1.5.Level

The LEVEL area - **(E)** in Fig. 13 - displays pulse length; the LEVEL select keys increase or decrease it from 0.2ms to 80ms. The pulse width is dependent on the FREQUENCY and LEVEL selections made.
Note that the level parameter is strictly connected to the pulse length but the value shown on the screen is not directly the pulse length: see Table 9 on page 19.

Table 10 shows the available values for the "level" parameter: note that the admitted range depends on the selected frequency - i.e. if frequency is set to 80Hz, level cannot be lower than 2.0 -.

Each time frequency is increased, the SmartXide system verifies if the currently selected value for the "level" parameter is correct according Table 10 and automatically changes it to the minimum admitted value if necessary.

Table 10: Available values for the "Level" parameter vs. frequency

Frequency	Available values for the "Level" parameter																				
5Hz	0.5	1.0	1.5	2.0	2.5	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10	11	12	13	14	15	20	30	40
10Hz	0.5	1.0	1.5	2.0	2.5	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10	11	12	13	14	15	20	30	40
20Hz	0.5	1.0	1.5	2.0	2.5	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10	11	12	13	14	15	20	30	40
50Hz	---	---	1.5	2.0	2.5	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10	11	12	13	14	15	20	30	40
80Hz	---	---	1.5	2.0	2.5	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10	11	12	13	14	15	20	30	40
100Hz	---	---	---	2.0	2.5	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10	11	12	13	14	15	20	30	40

For each given frequency, the higher is the level selected, the longer is the pulse length and therefore the greater is the average output power and the energy released: see also Table 9 on page 19 -.

See also par. 3. in this Section for the description of the power evaluation procedure performed by the system each time the "level" is changed.

1.6.Aiming source

The two keys "+" and "-" in the "Aiming" area - **(F)** in Fig. 13 e in Fig. 14 - adjust the intensity of the aiming beam from OFF to 100% (step: 2% between OFF and 10%, step: 10% for the other values).

ATTENTION!

If the aiming beam spot is not present at the distal end of the delivery system, its intensity is reduced or it looks diffused, this is a possible indication of a damaged or not properly working delivery system.
In these cases, the operator is recommended not to use the system and immediately call technical assistance.

1.7.DOT Scanner (*optional*)

The SmartXide system is provided by factory with the hardware and software needed to use a scanning unit called DOT Scanner available with the system accessories - *optional* -.
If the external DOT Scanner is present, the system automatically detects its presence and allows to activate it via the control panel by pressing the area shown as **(G)** in Fig. 13 and in Fig. 14.
The screen displays the message shown in Fig. 15 to warn the user that the delivery system selection has been changed; moreover the user is reminded to control the DOT Scanner connections.

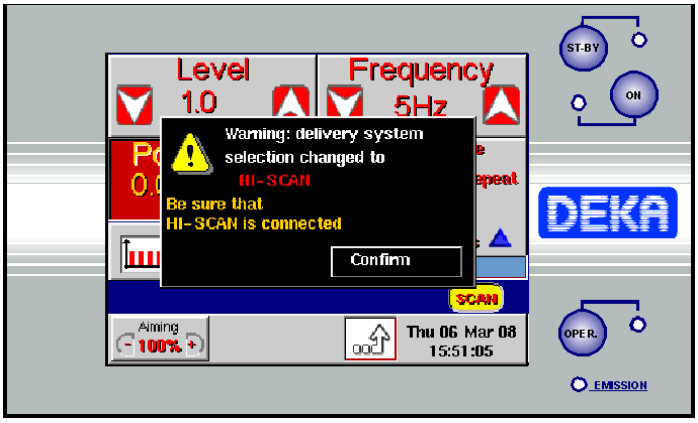


Fig. 15 - Message displayed when the DOT Scanner is activated

ATTENTION!

Pay attention not to press the keys on the scanning head while activating the DOT Scanner otherwise a "HS keyboard" alarm is stated - see the "Faults and troubleshooting" Section -.

Press the "Confirm" key to display the user menu when the DOT Scanner is activated.

1.8.Returning to the preliminary menu

Press the area corresponding to the icon **(H)** in Fig. 13 and Fig. 14 in order to return to the preliminary menu.
This operation can only be enabled in STAND-BY status, otherwise the system will reply with an acoustic and visual signal indicating an action which is not permitted.

2. DOT Scanner

An optional accessory of the SmartXide system is the DOT Scanner shown in Fig. 8 on page 25; it can be connected to the articulated arm - see par. 1.3. on Section "Installation" for the installation - and allows to achieve high performance in the "skin resurfacing" treatments.
This perfomance can be obtained by the DOT Scanner working at low, medium and high density; the area is treated by scanning the lines from left to right and from right to left, starting at the first line from the top to the last line at the bottom - see Fig. 16 -.

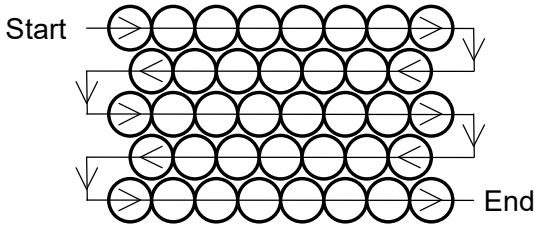


Fig. 16 - Example of scanning mode

2.1. Use of the DOT Scanner

To activate the external DOT Scanner, if properly installed, press the "SCAN" area in the User menu - **(G)** in Fig. 13 and in Fig. 14 - and press the "Confirm" area in the warning message shown in Fig. 15.
Once the DOT Scanner has been activated, the screen changes as shown in Fig. 17: the system enables the standard scanning mode.

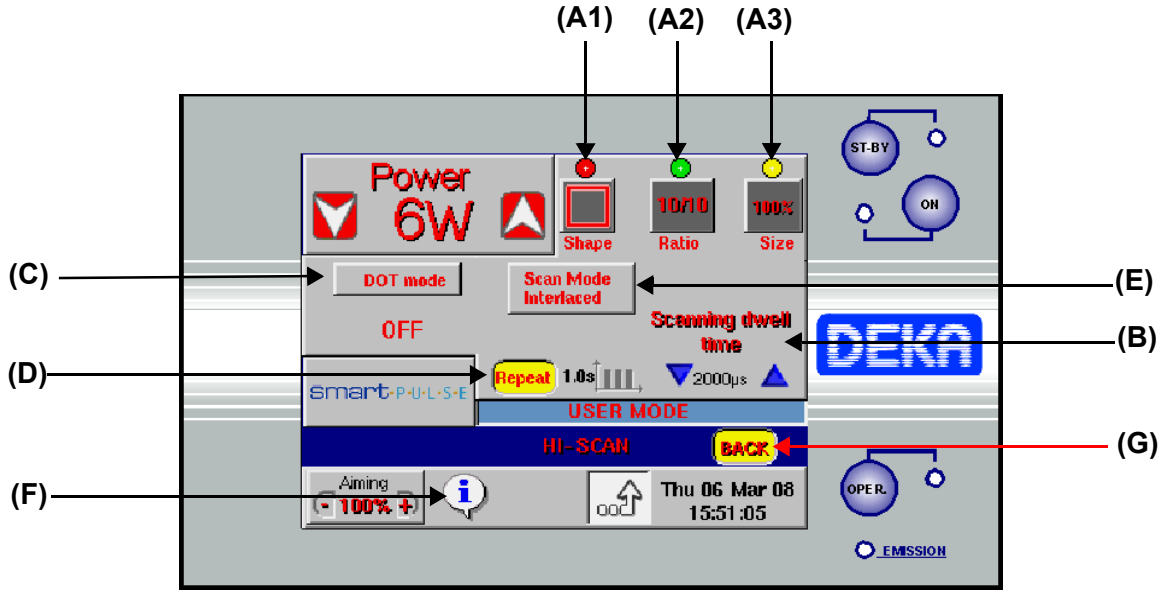


Fig. 17 - User menu when the DOT Scanner is activated

As long as the DOT Scanner is activated:

- ✓ the emission mode is fixed and cannot be changed;
- ✓ user can select power and the "Scanning dwell time" - **(B)** in Fig. 17 -, that is the length of the DOT Scanner's emission, from 200 s to 20000 s or, *if the DOT mode is activated* (see the description of the **(C)** area), from 200 s to 2000 s;
- ✓ the scanning head allows to move both the aiming beam and the CO_2 laser beam according to a pattern whose shape and dimension can be selected by the user using <u>one of the two following way</u>:

1. by the three keys located on the scanning head:

the ***red key*** allows to change the shape of the scanning area;
the ***yellow key*** allows to change the dimension of the scanning area;

the **green key** allows to change the height-width rate of the scanning area;

1. by the three areas located on the upper left part of the screen:

   the ***Shape*** area - **(A1)** in Fig. 17 - allows to change the shape of the scanning area;
   the ***Ratio*** area - **(A2)** in Fig. 17 - allows to change the height-width rate of the scanning area;
   the ***Size*** area - **(A3)** in Fig. 17 - allows to change the dimension of the scanning area - shown as percentage of the maximum available scanning area (15mm x 15mm) -.

NOTE

The three coloured circles located above the "Shape", "Ratio" and "Size" areas are useful to remind the corrispondence to the three keys located on the scanning head.

NOTE

The DOT Scanner moves the red aiming beam on the outline of the selected scanning area.
This function allows to immediately check the characteristics - shape and dimensions - of the scanning area.

Fig. 18 shows the available patterns for the DOT Scanner unit:

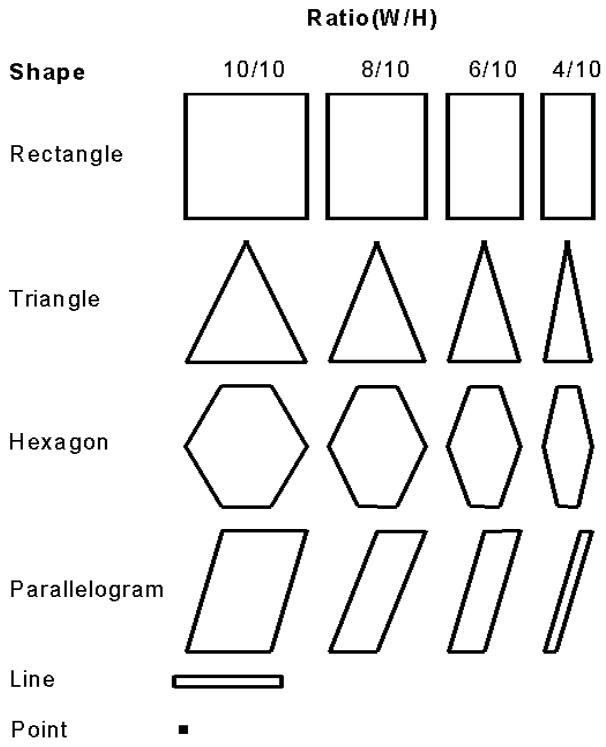


Fig. 18 - List of available patterns

✓ User can activate the "DOT" scanning mode just pressing the "**DOT mode**" area - **(C)** in Fig. 17 -. The system asks for confirmation.
In the "DOT mode" scanning modality the skin area is treated by scanning dots: the user can set the distance between contiguous dots focusing the laser power to be delivered on localized points without damaging surrounding tissues (see the example in Fig. 19).

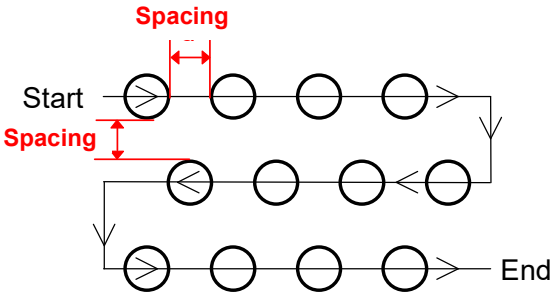


Fig. 19 - "DOT" scanning mode

The screen changes as shown in Fig. 20: user can select the "Spacing" parameter, that is the "distance" between the scanning dots, from 200 m to 2000 m (step: 50 m increments) by pressing on the two "arrow" keys shown as **(C1)** in Fig. 20.

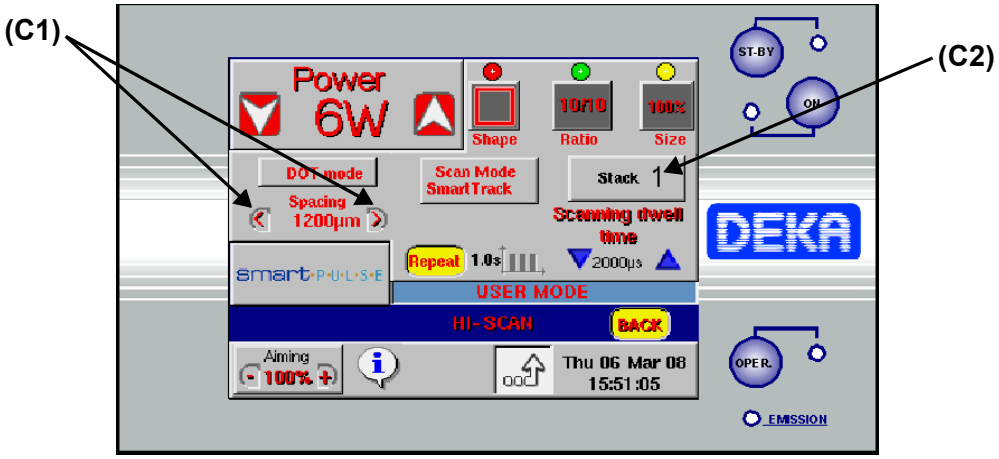


Fig. 20 - DOT mode - "Spacing" parameter

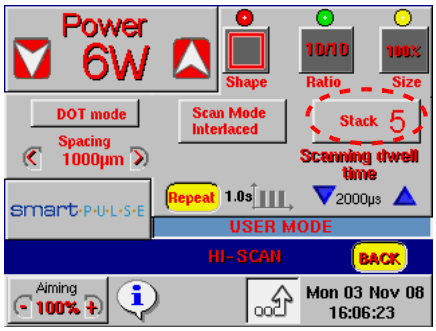
Moreover, the user can select and modify the "**Stack**" parameter, that manages the number of pulses consecutively delivered by the system on the same "dot".
This value can be selected from 1 to 5 by pressing the "Stack" area - **(C2)** in Fig. 20 - as many times as the number of pulses you want to select.

For example, if value "1" is selected, the SmartXide system performs only one pulse on every single dot while if value "3" is selected, the system performs three pulses on the same dot, before moving to another spot/dot.
The system asks for confirmation every time tha stack parameter is changed.

This scanning mode (i.e. Stack 3) should have the same effect on tissue like three consecutive scanning passes, but it has the advantage to enhance the superposition of the three shots over the same dot.

CAUTION!

However, this mode implies also a multiplication of the energetic factor on the tissue.
For this reason, if the "Stack" value is higher than "1", the selected number is highlighted in red color to warn the user (see the example below).



✓ The system allows to control the exposure scanning time.
Touch the area shown as **(D)** in Fig. 17 to enter the screen which allows to change the exposure mode - Fig. 21 -.

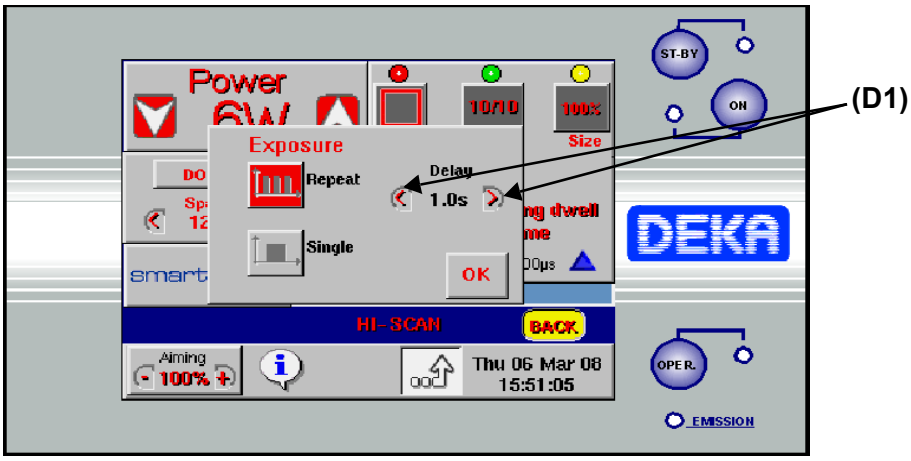


Fig. 21 - "Exposure" mode selection

Two exposure modes can be selected by touching the respective areas - Fig. 21 -:

- single scanning ("**Single**" on the screen);
- timed repeated scannings ("**Repeat.**" on the screen).

Single scanning

When the single exposure mode is enabled and footswitch is pressed, the system opens the shutter and keeps it open only for the time of one complete scanning.
Once this time is exhausted, the shutter is automatically closed regardless if footswitch is still pressed.
If the operator wants to perform a new exposure, he has to release and then press again footswitch.

Timed repeated scanning mode

When this mode is enabled and footswitch is pressed, the system opens the shutter and performs scanning sequences until footswitch is kept pressed.
Once a single scanning is completed, the shutter is automatically closed then, if footswitch is still pressed, the system waits the selected "Delay" time; after this time the shutter is open again and a new scanning is performed. This sequence is continuously repeated as long as footswitch is kept pressed.
Use the arrow keys ashown as **(E1)** in Fig. 21 to change the "delay" time between two scans from 1s to 5s (step: 0.5s).

✓ It is possible to select the scan mode among **Normal**, **Interlaced** or **SmartTrack** just touching the area shown as **(E)** in Fig. 17:

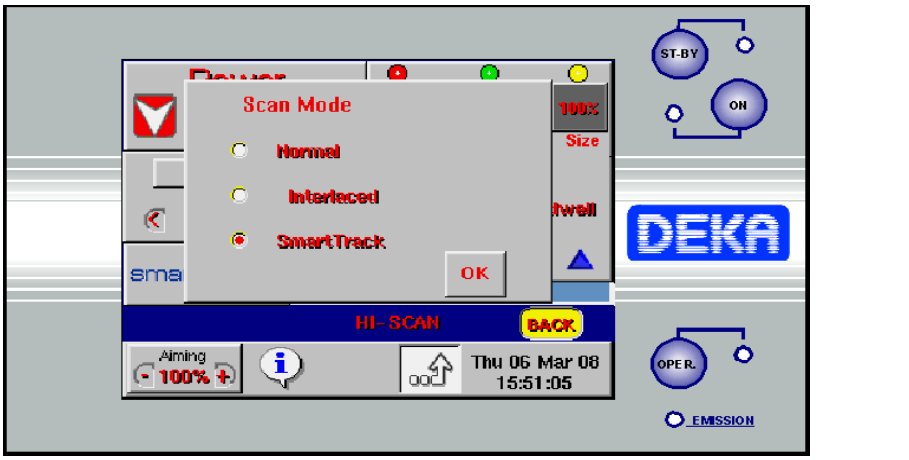


Fig. 22 - Scan mode selection

NOTE **The "SmartTrack" scan mode is enabled ONLY IF the "DOT mode" is ON.**

"Normal" scan mode

When this scan mode is selected, the area is treated by scanning the lines from left to right and from right to left, starting at the first line from the top to the last line at the bottom.

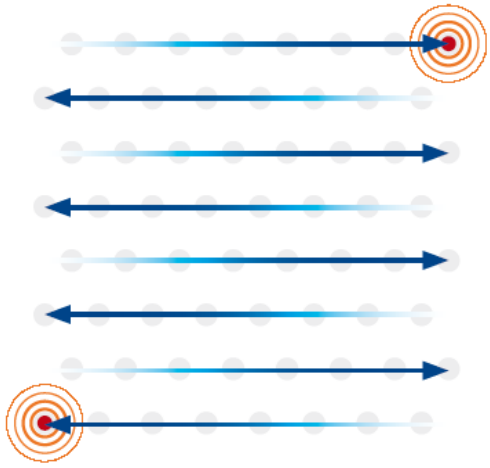


Fig. 23 - Example of "Normal" scan mode

"Interlaced" scan mode

When this scan mode is selected, the area is treated by first scanning the odd lines and then the even lines. Once the scan of the odd lines has been completed from the top to the bottom the even lines are scanned from the bottom to the top.

The interlaced scan mode is advisable for reducing the thermal effects during treatment.

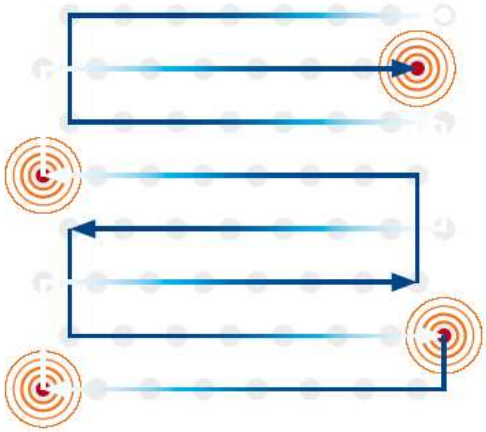


Fig. 24 - Example of "Interlaced" scan mode

"SmartTrack" scan mode

When this scan mode is selected, the area is treated scanning the dots with random order: this minimizes the tissue overheating and then the thermal damage.

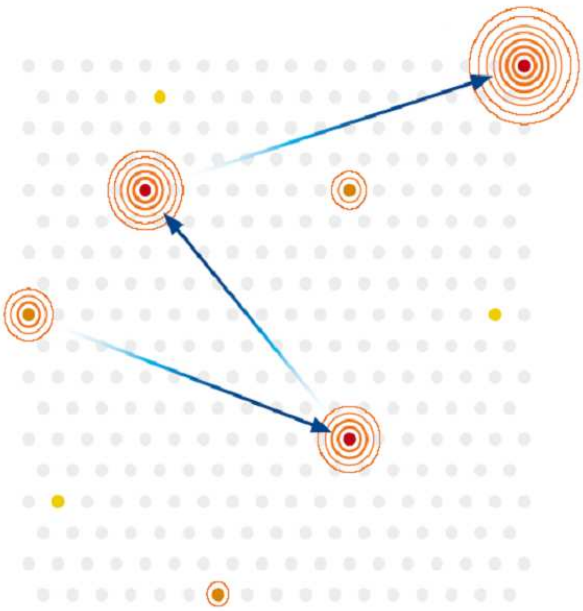


Fig. 25 - Example of "SmartTrack"scan mode

✓ It is possible to display a screen containing additional information about the scanning, by pressing the area shown as **(F)** in Fig. 17.
In particular, the system displays the value, according to the selected parameters, of the energy released on each scanning point ("Energy x DOT"), of the fluence (energy density) and of the percentage of treated surface ("Density" of "DOTs") - an example is shown in the following figure -.

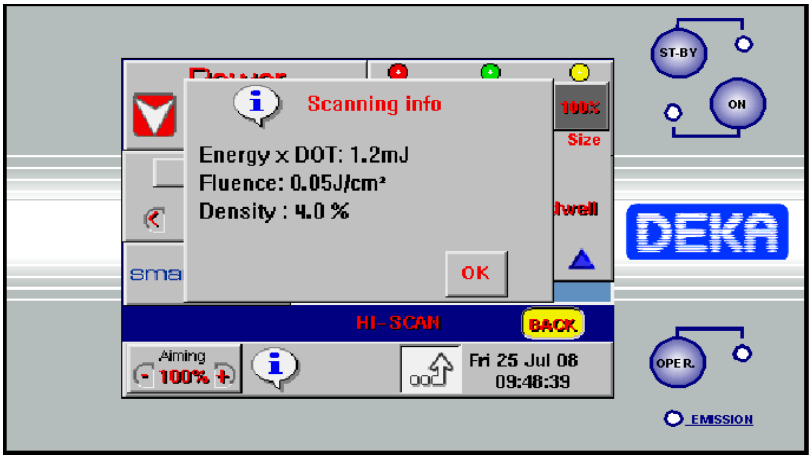


Fig. 26 - Scanning info

2.2.Disabling the scanning

If an area is to be treated without scanning, there is no need to unscrew the scanning head: just select the "Point" shape or press and keep pressed for a few seconds the red key on the scanning head until the red aiming beam stops at the center of the area given by the spacer of the scanning head. The laser emission will be performed on this point.

2.3.Enabling the scanning

Select a scanning shape different from point or press and keep pressed for a few seconds the red key on the scanning head until the red aiming beam starts moving again on the outline of the selected scanning area.

2.4.Deactivating the DOT Scanner

Touch the area of the screen shown as **(G)** in Fig. 17: the SmartXide system displays the message shown in Fig. 27 to warn the user that the delivery system selection has been changed;
moreover the user is reminded to ***connect the handpiece***.

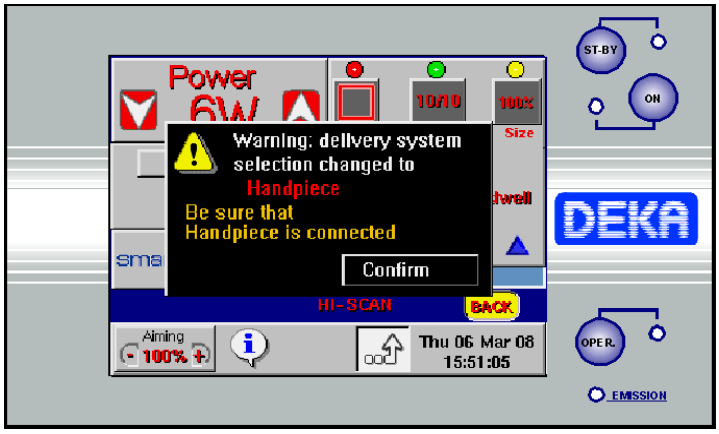


Fig. 27 - Message displayed when the DOT Scanner is deactivated

Press the "Confirm" key to go back to the user menu.

3. Power evaluation and calibration procedure

The SmartXide system is equipped with an internal power meter which allows to measure the real output power level of the CO_2 laser source.
The power evaluation and calibration procedure is started and continuously performed as the CO_2 source is switched on.

3.1.Power calibration in CW mode

When CW mode is selected, the operator can select the output power level between 2W and 30W.
As the CO_2 source is switched on and each time the power level is changed when the source is already switched on, the SmartXide system starts flashing the message "POWER EVALUATION" on the screen in order to warn the user that a power evaluation and calibration procedure for that power level is in progress.
During this procedure, footswitch is automatically disabled - red LED on the OPERATE key switched off - so no laser treatment can be started.
Note that if the OPERATE mode was selected, the system will restore this mode only once the procedure will be completed.
The procedure is intended to verify the real power level provided by the CO_2 laser source and eventually make it match with the power level selected by the operator.
At the end of the procedure, the message "POWER EVALUATION" is cleared.
The following two conditions can occur:

- ✓ the real power level matches with the selected power level or the procedure succeeds in making them match: no further message is displayed and the system is ready to operate;
- ✓ the real power level does not match with the selected power level AND the procedure fails in making them match: in this case, a double warning sound is performed and the real power level currently available is flashed on the screen for about 5s to warn the operator.
  After 5s, this value stops flashing and it is taken as the effective treatment power level.

Once the calibration procedure is completed, the SmartXide system starts monitoring the real power level in order to detect power fluctuations.
If the real power level changes so that it does not match anymore with the value displayed on the screen, the system acts as follows:

- ✓ if a *laser treatment is in progress* that is if footswitch is pressed and as long as it is kept pressed, the new power level is displayed on the screen with black characters on white background and the internal buzzer produces 5 sounds per seconds - instead of 1 sound per second - in order to warn the operator;
  if the power mismatch is recovered, the old power level is displayed on the screen with standard characters and timed sound is again performed one time per second.
- ✓ If *no laser treatment is in progress*, a double warning sound is performed and the new power level is flashed on the screen for about 5s to warn the operator.
  After 5s, this value stops flashing and it is taken as the new effective treatment power level.
- ✓ if the detected output power is out of the regulatory limits on respect to the nominal one, the emission is immediately stopped and the system states an HIGH POWER or a LOW POWER alarm - see par. 2.9. on Section "Faults and troubleshooting" -.

3.2.Power evaluation in PW mode

When PW mode is selected, the power level displayed on the screen is the average power level resulting from the selected frequency and level values: the operator can change the power level only acting on the frequency and level parameters.
As the CO_2 source is switched on and each time frequency or level are changed when the source is already switched on, the SmartXide system starts flashing the message "POWER EVALUATION" on the screen in order to warn the user that a power evaluation procedure is in progress.
During this procedure, footswitch is automatically disabled - red LED on the OPERATE key switched off - so no laser treatment can be started.
Note that if the OPERATE mode was selected, the system will restore this mode only once the procedure will be completed.
The procedure is intended to read the real average power level provided by the CO_2 laser source. No calibration is performed.
At the end of the procedure, the message "POWER EVALUATION" is cleared and the measured real power level is displayed on the screen: this value is taken as the reference value for further power tests.
Once the calibration procedure is completed, the SmartXide system starts monitoring the real power level in order to detect power fluctuations.
If the real power level changes so that it doesn't match anymore with the value displayed on the screen, the system acts as follows:

- ✓ if *a laser treatment is in progress* that is if footswitch is pressed and as long as it is kept pressed, the new power level is displayed on the screen with black characters on white background and the internal buzzer produces 5 sounds per seconds - instead of 1 sound per second - in order to warn the operator.
  if the power mismatch is recovered, the old power level is displayed on the screen with standard characters and timed sound is again performed one time per second.
- ✓ if *no laser treatment is in progress*, a double warning sound is performed and the new power level is flashed on the screen for about 5s to warn the operator.
  After 5s, this value stops flashing and it is taken as the new effective treatment power level.
- ✓ if the detected output power is out of the regulatory limits on respect to the nominal one, the emission is immediately stopped and the system states an HIGH POWER or a LOW POWER alarm - see par. 2.9. on Section "Faults and troubleshooting" -.

Page intentionally left blank.

Clinical information

This section discusses in general terms about the SmartXide system from the clinical point of view (indications, contraindications, adverse effects).

1. Indications

The SmartXide system is a medical equipment indicated for the incision, excision, ablation, vaporization and coagulation of body soft tissues including intraoral tissues, in medical specialties including aesthetic (dermatology and plastic surgery), otolaryngology (ENT), gynaecology, neurosurgery and genitourinary surgery.
The use with the scanning unit is indicated for ablative skin resurfacing.

2. Contraindications

There are no known contraindications for the use of the SmartXide system, apart general contraindications as in standard surgery.

3. Adverse Effects

Both bacterial and viral infections are potential side effects if proper clinical precautions are not observed. Complications, though rare, can occur and should be discussed and understood. The patient must understand the importance of pretreatment and posttreatment instructions, and that failure to comply with these instructions may increase the probability of complications.

4. Precautions

Subjects with a history of Herpes may be prescribed prophylactic drugs one week prior to treatment.

5. Pretreatment Recommendations

At the time of the initial visit, the physician should determine the suitability of the laser treatment and inform patients about the treatment.

6. Posttreatment Recommendations

After each treatment session, physicians should advise their patients on proper care of the treated area.

✓ Discomfort may be relieved by ice packs.

✓ Patient is to contact the physician if there is any indication of infection (redness, tenderness or pus).

Faults and troubleshooting

This sections describes the faults detected by the system and provides a troubleshooting of some problems that can be identified and solved by the operator.

1. Faults management

The SmartXide system is able of detect fault conditions that may be dangerous for the subject under treatment and for the system itself.
As soon as one of these conditions is detected, the system automatically switches to safety mode: tthe shutter is closed, the CO_2 source is turned off and footswitch is disabled.
The SYSTEM FAULT menu - see Fig. 28 - is immediately displayed on the screen.

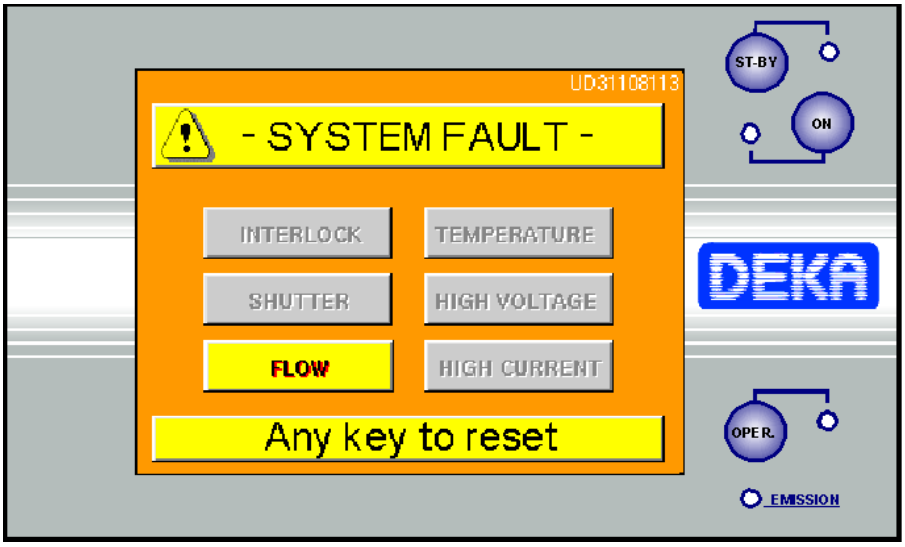


Fig. 28 - SYSTEM FAULT menu

The SmartXide system displays a summary table which reports all the fault conditions which can be detected: the labels corresponding to the currently detected fault conditions are written with black characters on yellow background - i.e. in Fig. 28 a FLOW fault was detected -.
Moreover, once a fault is detected, the SmartXide system keeps on displaying the relative label with black characters on red background even if the fault is solved: this allows the operator to record the detected faults to eventually inform the technical assistance service.
The message "Any Key to reset" tells the user he has to press a key to quit the fault menu and go back to the operative menu.

2. Descriptions of Faults

The possible faults and the appropriate action to take are detailed below.

2.1.Interlock

This fault is displayed if the INTERLOCK system detects an open circuit.
If the INTERLOCK feature is attached to an external interlock device, check that the door is closed, that the external interlock device is functioning and that the cable from the external interlock device is properly attached to the socket on the laser labeled INTERLOCK.
If an external interlock device is not used, check that the INTERLOCK jumper (provided with the laser accessories) is properly attached to the socket labeled INTERLOCK.
Press any key to reset the fault display.
Call Technical Service if this fault persists.

2.2.Temperature

This fault is displayed if the temperature of the cooling fluid inside the CO_2 laser source or the temperature of the high voltage power supply unit gets too high.

Do not turn off the system in order to let the cooling fluid cool it down.

Wait approximately 2 minutes, and then press any key to reset the fault display.
Call Technical Service if this fault persists.

2.3.Shutter

This fault is displayed if the shutter's detected position is not the same as the shutter's expected position. Press any key to reset the fault display.
Call Technical Service if this fault persists.

2.4.High voltage

This fault is displayed if the internal high voltage power supply unit is not properly working.
Press any key to reset this fault display, then switch on the laser source again.
Call Technical Service if this fault persists.

2.5.Flow

This fault is displayed if poor flow in the cooling circuit is detected.
Press any key to reset the fault display.
Call Technical Service if this fault persists. Only Deka technical assistance service or skilled personnel authorized by Deka may service the cooling circuit.

2.6.Cur.thres.

At the start up, during the internal self test procedure, the system verifies the maximum CW current value provided by the internal high voltage power unit to the CO_2 laser source.
If this value is too low, the "CUR.THRES." fault is stated.
The "CUR.THRES." fault can therefore be stated only at the start up.
Note that the internal tests which may cause an "HIGH CURRENT" fault are based on the current value

measured at the start up.
Turn off the system then turn it on again: call the technical assistance service if the "CUR.THRES." fault persists or an "HIGH CURRENT" fault is detected.

2.7.Current zero

When the CO_2 laser source is switched on and the CW emission mode is selected, the system continuously checks the value of the current provided by the internal high voltage power unit to the CO_2 laser source.
If this value is too low, the "CURRENT ZERO" fault is stated.
Reset the fault condition, then try to switch on the laser source again: call the technical assistance service if the fault persists.

2.8.High current

When the CO_2 laser source is switched on and the CW emission mode is selected, the system continuously checks the value of the current provided by the internal high voltage power unit to the CO_2 laser source.
If the current value is too high with respect to the selected power level, the "HIGH CURRENT" fault is stated.
Note that the internal tests which may cause an "HIGH CURRENT" fault are based on the current value measured at the start up.
First of all, reset the fault condition, then switch on the laser source again.
If the fault persists, turn off the system then turn it on again in order to make the system measure again the reference current value.
Call the technical assistance service if the "CUR.THRES." fault is stated or the "HIGH CURRENT" fault persists.

2.9.High power/Low power

These two fault conditions are stated if the power evaluation procedure detects a wrong output power level.
The "High power"/"Low power" label is displayed in the SYSTEM FAULT menu in the same location of "High current" alarm.
Carefully read par. 3. on Section "Use of the control panel".
Reset the fault condition, then try to switch on the laser source in order to perform once again the power evaluation procedure.
Call the technical assistance service if the fault persists.

2.10.EEPROM

This fault condition is stated if an internal memory component does not work properly.
It can be stated at the start up of the system or when the CO_2 laser source is switched off - STAND BY key pressed -.
This fault is not critical as concerns the performances of the system but there might be problems with the management of the treatment programs that is the system might forget the changes made by the operator to the treatment programs.
Try to reset the fault condition, if it persists call the technical assistance service.

2.11.Hi-Scan

This fault concerns troubles with the DOT Scanner.
The label "HI-SCAN" is displayed in the same box used for the "HIGH CURRENT" alarm.
Try to reset the fault condition.
Call the technical assistance service if the fault persists.

2.12.HS KEYB

On the scanning head there are three keys.
The system states a fault condition if one of these keys is pressed when the DOT Scanner is activated.
The label "HS KEYB" is displayed in the same box used for "HIGH CURRENT" alarm.
Try to reset the fault condition.
If it persists call the technical assistance service.

2.13.HS galvo driver

The system states a fault condition if the mirrors inside the DOT Scanner are not properly working.
The label "HS galvo driver" is displayed in the same box used for "HIGH CURRENT" alarm.
If this fault is stated on DOT Scanner activation, check all the connections with the scanning unit.
Try to reset the fault condition.
If it persists call the technical assistance service.

2.14.HS points maker

This fault concerns troubles with the software of the DOT Scanner.
The label "HS points maker" is displayed in the same box used for "HIGH CURRENT" alarm.
Try to reset the fault condition.
If it persists call the technical assistance service.

2.15.Warnings

If the system detects power fluctuations (emission mode set to either CW and PW), the power level on the screen may be displayed with yellow characters instead of red characters once calibration is completed. If laser treatment is in progress when this occurs, the warning tone rate increases. These two conditions are warnings, not fault conditions. The system does not go into standby and the operator can continue with the laser treatment.

3. Troubleshooting

The next table provides a troubleshooting of some problems that can be identified and solved by the operator.

Table 11: Troubleshooting

PROBLEM	HOW TO MANAGE IT
System does not turn on	✓ Make sure the mains cable is properly connected and the mains voltage/current values match with the specifications of the system. ✓ Check if the key switch and the emergency switch are correctly positioned. ✓ Disconnect the mains cable, wait three (3) minutes, then check the fuses located in the mains cup socket - see par. 4. in this Section -.
Nothing happens as footswitch is pressed	✓ Make sure the system is in the OPERATE state - see the "System description" Section -. ✓ Make sure footswitch is properly connected to the apposite connector - see the "System description" Section -.
Poor laser emission or no laser emission from the articulated arm	Call Technical Assistance Service.
Aiming beam and CO_2 beam not coaxial	✓ Make sure the articulated arm was properly installed. ✓ The problem may be due to a misalignment of the articulated arm: call Technical Assistance Service.
Power displayed after calibration is different from power selected.	System cannot provide power selected. Read carefully par. 3. on Section "Use of the control panel".
The system does not detect the DOT Scanner presence.	Make sure DOT Scanner is properly connected. Read carefully par. 1.3. on Section "Installation".

4. Fuses check and replacing

If the SmartXide system cannot be turned on, fuses should be checked.

CAUTION **Always turn off the system and disconnect the mains cable before checking or replacing the fuses.**

The fuses - Fig. 29, (B) - are located inside the mains cup socket - Fig. 29, (A) -.

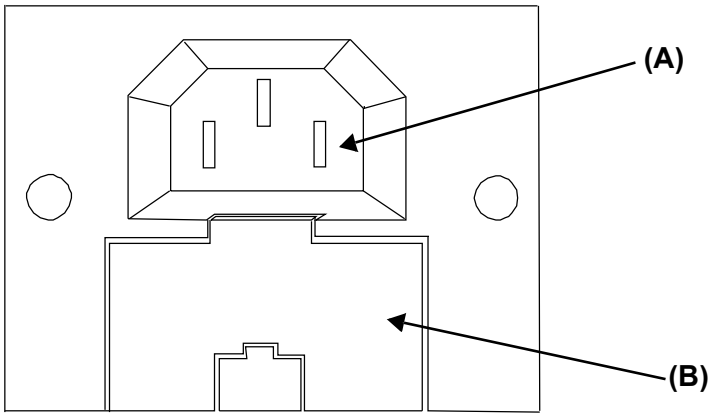


Fig. 29 - Fuses location

Proceed as follows to replace fuses:

1. open the fuses housing slot as shown in Fig. 30: open the door of the fuses housing using a screwdriver as shown in figure.

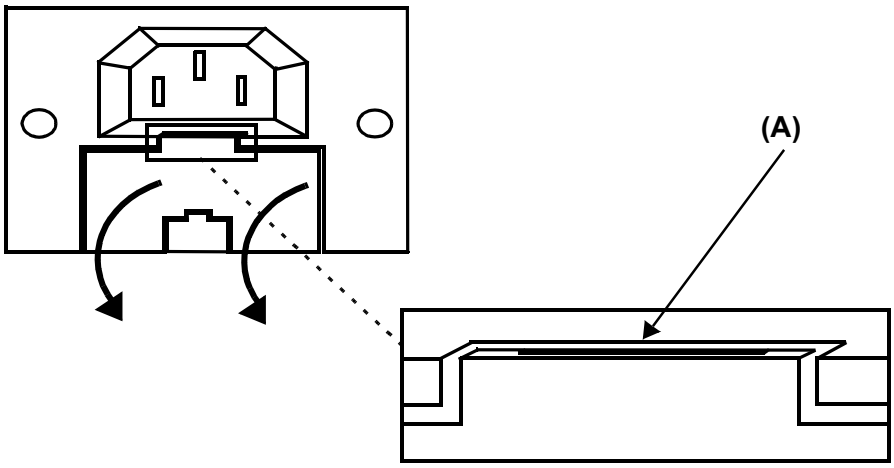


Fig. 30 - Opening the fuses houses

2. fuses are housed in other two separate containers which must be taken off the housing: push at the same time towards bottom and outwards the blocking tag as shown in Fig. 31.

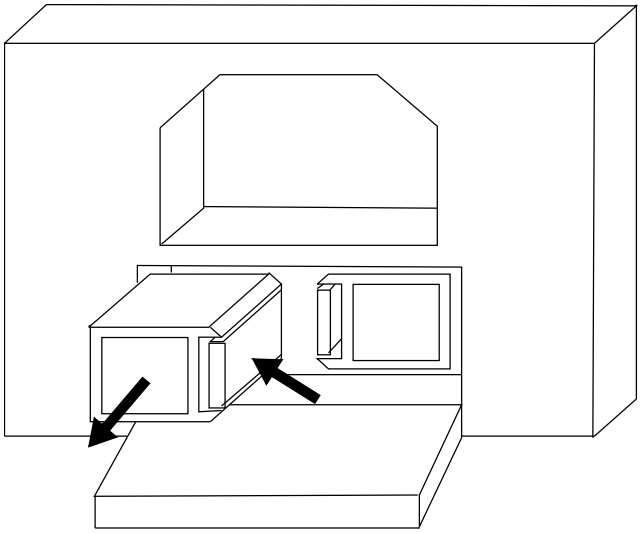


Fig. 31 - Taking out of the fuses

NOTA **The damaged fuses must be replaced only with fuses of the same kind (see Table 5 on page 18 or label 5 in Fig. 2 on page 5).**

3. place the fuses containers and close the fuses housing slot.

Try again to turn on the SmartXide system: if the system cannot still be turned on, call Technical Assistance.

Page intentionally left blank.

Maintenance

This section of the manual discusses maintenance practices such as cleaning, disinfecting and sterilizing equipment.

1. Maintenance for system reliability

NOTE **All these maintenance procedures should be carried out at least once per year by qualified personnel authorized by Deka.**

The following maintenance procedures should be performed in order to assure system reliability:

- ✓ laser source inspection;
- ✓ internal power meter inspection and calibration;
- ✓ check of the electric insulation.

The SmartXide system is a HIGH FAIL-SAFE device.
Nevertheless, according to the standard EN60601-2-22, it is necessary to perform preventive maintenance procedures on some components such as:

- ✓ shutter;
- ✓ footswitch.

2. Ordinary maintenance

2.1. General rules for cleaning

Daily cleaning

- ✓ Remove (with vacuum cleaners) any eventual solid residue (dust, particles etc.);
- ✓ use neutral and non-abrasive detergents;
- ✓ dry with soft, clean cloths or chamois.

Precautions

- ✓ Take care that detergent does not penetrate cavities or apertures of the device;
- ✓ do not use chemical solvents and/or abrasive detergents;
- ✓ do not use alcohol to clean the surface of the display.

2.2.Handpiece Care

Cleaning

Remove visible debris with a suitable solution such as soap and water. Use a cloth to clean exterior surfaces and a bottlebrush to clean interior surfaces, being careful to avoid lens surfaces.

Disinfecting

Immerse the handpiece components in a hospital-grade disinfectant following the disinfectant manufacturer's instructions.

Sterilizing

Cold soak sterilants or steam sterilization may be used.
For steam sterilization the following protocol is recommended:

1. disconnect the handpiece from the system and unscrew the handpiece's tip;
2. place the tip in a double autoclave pouch and put the pouches in the autoclave;
3. set the pressure and the temperature of the autoclave following the autoclave manufacturer's instructions for surgical instruments.

NOTE **Store the handpiece and the tips in a sterile environment or sterilize just before use to minimize the chance of contamination.**

NOTE **The articulated arm can be wrapped in sterilized gauges but always avoid wrapping it too tight that is avoid any mechanical stress.**

2.3.Disinfection of the DOT Scanner spacer

As the DOT Scanner spacer is the only part which comes in touch with the skin, only this part may be disinfected "by immersion" in a hospital-grade disinfectant solution.
Before disinfecting the spacer, unscrew it from the DOT Scanner head.
Follow the timings and concentrations given by the manufacturer of the disinfectant.

2.4.Focusing lens cleaning

The focusing lens should be checked by the operator after any important treatment or at most every 10 treatments.
Proceed as follows:

1. loosen the lens holder from the handpiece;
2. clean the lens' surfaces with optic paper soaked in acetone;
3. blow the residuals with a clean and dry air flow.
4. reposition the lens inside the lens holder.

CAUTION!

- ✓ **The focusing lens is very fragile.**
  Care is recommended during assembly and disassembly.
- ✓ **Avoid scratching the surface while cleaning.**
  Remember that cotton and some types of paper contain glass fibers that can scratch the surface of the lens.
- ✓ **Use only recommended products.**

2.5. Emergency switch and interlock

ATTENTION!

Check the correct working of the emergency switch and of the interlock network once a month.

3. Maintenance to be carried out by skilled personnel

The following procedures must be carried out by ***qualified personnel authorized by DEKA at least once a year***:

- ✓ laser source inspection;
- ✓ internal power meter inspection and calibration;
- ✓ check of the electric insulation.
- ✓ check of the cooling fluid level.
  The cooling fluid of the SmartXide system is composed of a mixture of fluorurates C5-C18 (the great part with 8 atoms of carbon).

CAUTION!

Do not introduce in the cooling circuit liquids other than the one supplied or recommended by DEKA.
The use of improper liquids can permanently damage the circuit.

CAUTION!

THE COOLING FLUID MUST NOT BE DISPOSED IN THE ENVIRONMENT.
The disposal of the cooling fluid should be performed according to national and local laws.

Page intentionally left blank.

Accessories

The SmartXide system is provided with the accessories listed in the table below:

Table 12: Accessories

NAME	CODE	QUANTITY
INTERLOCK CONNECTOR	N21901	1
FOOTSWITCH	E094A1	1
MAINS CABLE	021300055	1
SYSTEM KEY	041400050	2
HANDPIECE 4" including: Open terminal	N324D2 04255022A	1 1
HANDPIECE 2" including: straight terminal	N377B1 04255025A	1 1
HANDPIECE BODY	04299003B	1
SCANNING KIT including: EXTERNAL HI-SCAN UNIT (E124G2) INTERNAL ELECTRONICS (F09801) The external Hi-Scan unit includes: HI-SCAN CABLE (W00253) HI-SCAN HEAD (E109G1) The internal electronics includes: HI-SCAN BOARD (C280A2) ADAPTER BOARD (C340A1) INTERNAL CABLE (W00226) INTERNAL CABLE (W00262)	F095G2	optional
LASER SAFETY GOGGLES @ 10.6 m	070100038	2
LASER COVER	04296009A	1
DOOR LABEL	079101200	2
FUSES 6.3AT (6.3x32mm)	020900127	2
SYSTEM CASE	070400043	1
OPERATOR'S MANUAL	OM079R1_G.V09	1

Page intentionally left blank.

Appendix A

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSION		
The SmartXide system is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartXide system should assure that it is used in such an environment.		
EMISSION TEST	**COMPLIANCE**	**ELECTROMAGNETIC ENVIRONMENT**
RF Emissions CISPR 11	Group 1	The SmartXide system uses RF energy only for its internal function. Therefore, its RF emission are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The SmartXide system is suitable for use in all establishments including domestic establishments and those directly connected to the public low voltage power supply network that supply buildings used for domestic purposes.
Harmonic Emissions CEI EN 61000-3-2	Class A	
Voltage fluctuation/ flicker emissions CEI EN 61000-3-3	Complies	

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY			
The SmartXide system is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartXide system should assure that it is used in such an environment.			
IMMUNITY TEST	**CEI EN 60601-1-2 TEST LEVEL**	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT**
Electrostatic discharge (ESD) CEI EN 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst CEI EN 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines ±1kV for input/ output lines	Mains power quality should be that o a typical commercial or hospital environment.
Surge CEI EN 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that o a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines CEI EN 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that o a typical commercial or hospital environment. If the user of the SmartXide system requires continued operation during power mains interruptions, it is recommended that the SmartXide system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field CEI EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY

The SmartXide system is intended for use in the electromagnetic environment specified below. The customer or user of the SmartXide system should assure that it is used in such an environment.

IMMUNITY TEST	CEI EN 60601-1-2 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - RECOMMENDED SEPARATION DISTANCE -
Conducted RF CEI EN 61000-4-6	3 V_{RMS} 150 kHz÷80 MHz	3 V_{RMS}	$d = 1,2\sqrt{P}$
Radiated RF CEI EN 61000-4-3	3 V/m 80 MHz÷2,5 GHz	3 V/m	$d = 1,2\sqrt{P}$ from 80MHz to 800 MHz
			$d = 2,3\sqrt{P}$ from 800MHz to 2,5 GHz

Portable and mobile RF communications equipment should be used no closer to any part of the system including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance.

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:

Note:
(1) At 80MHz and 800MHz, the separation distance for the higher frequency range applies.
(2) The guidelines may not applied in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. to assess the electromagnetic environment due to fixed R transmitters, an electromagnetic site survey should be considered. if the measured field strength in the location in which the SmartXide system is used exceeds the applicable RF compliance level above, the SmartXide system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the SmartXide system.
(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE SMARTXIDE

The SmartXide system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SmartXide system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SmartXide system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz÷80 MHz $d = 1,2\sqrt{P}$	80 MHz÷800 MHz $d = 1,2\sqrt{P}$	800 MHz÷2,5 GHz $d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note:
(1): At 80MHz and 800MHz, the separation distance for the higher frequency range applies.
(2): The guidelines may not applied in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

CABLES AND ACCESSORIES WITH WHICH COMPLIANCE TO EN 60601-1-2 EMC REQUIREMENTS IS CLAIMED	
INTERLOCK CONNECTOR	N21901
FOOTSWITCH	E094A1
MAINS CABLE	021300055
HANDPIECE 4"	N324D2
HANDPIECE 2"	N377B1
EXTERNAL DOT Scanner	F095G2

ATTENTION!

The use of accessories, transducers and cable other that those above specified may increase electromagnetic emission and decrease electromagnetic immunity.

Page intentionally left blank.

Appendix B

Calibrating the power meter

CAUTION!

The following procedure should only be done by *trained personnel authorized by Deka*.
When the system enclosure is removed, hazardous voltages and/or laser radiation levels are exposed.

The SmartXide system is equipped with an internal power meter that allows the microprocessor to detect the real output power level generated by the CO_2 laser source. The signal from this power meter is first processed by the hardware on the CPU board before being read and converted by the A/C converter located inside the microcontroller.

Please contact the Manufacturer to arrange for an annual calibration.

The calibrating procedure is here described just for information:

1. enter the SERVICE menu.
2. be sure that the MODE key is set to CW on the touch screen display;
3. unscrew the handpiece from the articulated arm and attach an external power meter at the end of the articulated arm.
4. select a power level of 9 W on the control panel.
5. switch on the CO_2 laser source;
6. compare the power level read by the external power meter to the power level measured by the system;
7. regulate RP5 (GAIN) on the CPU board to get the same power level on the display as measured by the external power meter±0.2W;
8. switch on the laser source and regulate RP6 (SPEED UP) on the CPU board to make the power level shown on the display change from 0W to 9W in 4s without overshooting;
9. repeat step **8.** and step **9.** until these two conditions are met.

Page intentionally left blank.

DEKA M.E.L.A. S.r.l.
Via Baldanzese 17
50041 Calenzano
Firenze - Italy
Tel. (+39) 055 8874942 Fax (+39) 055 8832884
www.dekalaser.com